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Medicare Program; Prospective Payment System for Home Health Agencies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 413, 424, and 484

[HCFA–1059–F]

RIN 0938–AJ24

Medicare Program; Prospective Payment System for Home Health Agencies

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes requirements for the new prospective payment system for home health agencies as required by section 4603 of the Balanced Budget Act of 1997, as amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. The requirements include the implementation of a prospective payment system for home health agencies, consolidated billing requirements, and a number of other related changes. The prospective payment system described in this rule replaces the retrospective reasonable-cost-based system currently used by Medicare for the payment of home health services under Part A and Part B.

EFFECTIVE DATE: These regulations are effective October 1, 2000.

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In addition, because of the many terms to which we refer by abbreviation in this rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ADL	Activities of Daily Living
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
COPs	Conditions of participation

DME	Durable medical equipment
FIs	Fiscal intermediaries
FFY	Federal fiscal year
FMR	Focused medical review
FY	Fiscal year
HHA	Home health agency
HIC	Health insurance claim
HHRGs	Home Health Resource Groups
IADL	Instrumental Activities of Daily Living
IPS	Interim payment system
LUPA	Low-utilization payment adjustment
MS	Medical social services
MSA	Metropolitan Statistical Area
NCSB	Neurological, cognitive, sensory, and behavioral variables
OASIS	Outcome and Assessment Information Set
OBQI	Outcome based quality improvement
OCESAA	Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999
OSCAR	On-line Survey and Certification System
OT	Occupational therapy
PEP	Partial episode payment
PPS	Prospective payment system
PT	Physical therapy
RHHI	Regional Home Health Intermediary
RUGs	Resource Utilization Groups
SCIC	Significant Change in Condition
SN	Skilled nursing service
SP	Speech-language pathology

I. Background

A. Current System for Payment of Home Health Agencies

The Balanced Budget Act of 1997 (BBA), Public Law 105 33, enacted on August 5, 1997, significantly changed the way we pay for Medicare home health services. Until the implementation of a home health prospective payment system (PPS), home health agencies (HHAs) receive payment under a cost-based reimbursement system, referred to as the interim payment system and generally established by section 4602 of the BBA. The interim payment system imposes two sets of cost limits for HHAs. Section 4206(a) of the BBA reduced the home health per-visit cost limits from 112 percent of the mean labor-related and nonlabor-related, per-visit costs for freestanding agencies to 105 percent of the median. In addition, HHA costs are subjected to an aggregate per-beneficiary cost limitation. For those providers with a 12-month cost reporting period ending in Federal fiscal year (FFY) 1994, the per-beneficiary cost limitation is based on a blend of costs (75 percent on 98 percent of the agency-specific costs and 25 percent on 98 percent of the standardized regional average of the costs for the agency's census region). For new providers and those providers without a 12-month cost-reporting period ending in FFY 1994, the per-beneficiary limitation is the national median of the per-beneficiary limits for HHAs. Under the interim payment system, HHAs are paid the lesser of (1) actual reasonable costs; (2) the per-visit limits; or (3) the per-beneficiary limits. Effective October 1, 1997, the interim payment system exists until prospective payment for HHAs is implemented.

On October 21, 1998, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (OCESAA), Public Law 105–277, was signed into law. Section 5101 of OCESAA amended section 1861(v)(1)(L) of the Social Security Act (the Act) by providing for adjustments to the per-beneficiary and per-visit limitations for cost-reporting periods beginning on or after October 1, 1998. We had published a notice with comment period establishing the cost limitations for cost reporting periods beginning on or after October 1, 1998 in the **Federal Register** that was entitled ''Medicare Program; Schedules of Per-Visit and Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning On or After October 1, 1998'' on August 11, 1998 (63 FR 42912). OCESAA made the following adjustments to these limitations:

Providers with a 12-month cost reporting period ending during FY 1994, whose per-beneficiary limitations were less than the national median, which is to be set at 100 percent for comparison purposes, will get their current per-beneficiary limitation plus ⅓ of the difference between their rate and the adjusted national median per-beneficiary limitation. New providers and providers without a 12-month cost-reporting period ending in FFY 1994 whose first cost-reporting period begins before October 1, 1998 will receive 100 percent of the national median per-beneficiary limitation.

New providers whose first cost-reporting periods begin during FFY 1999 will receive 75 percent of the national median per-beneficiary limitation as published in the August 11, 1998 notice. In the case of a new provider or a provider that did not have a 12-month cost-reporting period beginning during FFY 1994 that filed an application for HHA provider status before October 15, 1998 or that was approved as a branch of its parent agency before that date and becomes a subunit of the parent agency or a separate freestanding agency on or after that date, the per-beneficiary limitation will be set at 100 percent of the median. The per-visit limitation effective for cost-reporting periods beginning on or after October 1, 1998 is set at 106 percent of the median instead of 105 percent of the median, as previously required in the BBA.

There was contingency language for the home health PPS provided in the BBA that was also amended by section 5101 of OCESAA. The language provided that if the Secretary, for any reason, does not establish and implement the PPS for home health services by October 1, 2000, the Secretary will provide for a reduction by 15 percent to the per-visit cost limits and per-beneficiary limits, as those limits would otherwise be in effect on September 30, 2000. Section 302 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–113, enacted on November 29, 1999, however, subsequently removed the contingency language governing the 15 percent reduction to the IPS cost limits for FFY 2001. It also increased the per-beneficiary limit for those providers with limits below the national median.

B. Requirements of the Balanced Budget Act of 1997, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999, and the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 for the Development of a Prospective Payment System for Home Health Agencies

Section 4603(a) of the BBA provides the authority for the development of a PPS for all Medicare-covered home health services paid on a reasonable cost basis that will ultimately be based on units of payment by adding section 1895 to the Act entitled ''Prospective Payment For Home Health Services.''

Section 5101(c) of OCESAA amends section 1895(a) of the Act by removing the transition into the PPS by cost-reporting periods and requiring all HHAs to be paid under PPS effective upon the implementation date of the system. Section 1895(a) of the Act now states ''Notwithstanding section 1861(v), the Secretary shall provide, for portions of cost reporting periods occurring on or after October 1, 2000, for payments for home health services in accordance with a prospective payment system established by the Secretary under this section.''

Section 1895(b)(1) of the Act requires the Secretary to establish a PPS for all costs of home health services. Under this system all services covered and paid for on a reasonable cost basis under the Medicare home health benefit as of the date of enactment of the BBA, including medical supplies, will be paid on the basis of a prospective payment amount. The Secretary may provide for a transition of not longer than 4 years during which a portion of the prospective payment may be agency-specific as long as the blend does not exceed budget-neutrality targets.

Section 1895(b)(2) of the Act requires the Secretary in defining a prospective payment amount to consider an appropriate unit of service and the number, type, and duration of visits furnished within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A)(i) of the Act requires that (1) the computation of a standard prospective payment amount include all costs of home health services covered and paid for on a reasonable-cost basis and be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate the effects of case-mix and wage levels among HHAs.

Section 5101(c) of OCESAA modifies the effective date of the budget-neutrality targets for HHA PPS by amending section 1895(b)(3)(A)(ii) of the Act. Section 1895(b)(3)(A)(ii) of the Act, as amended, requires that the standard prospective payment limitation amounts be budget neutral to what would be expended under the current interim payment system with the limits reduced by 15 percent at the inception of the PPS on October 1, 2000. Section 302 of the BBRA, delayed the application of the 15 percent reduction in the budget neutrality target for PPS until one year after PPS implementation. The law further requires the Secretary to report within 6 months of implementation of PPS on the need for the 15 percent reduction.

Section 5101(d)(2) of OCESAA also modifies the statutory provisions dealing with the home health market basket percentage increase. For fiscal years 2002 or 2003, sections 1895(b)(3)(B)(i) and (b)(3)(B)(ii) of the Act, as so modified, require that the standard prospective payment amounts be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute requires the rates to be increased by the applicable home health market basket index change. Section 306 of the BBRA amended the statute to provide a technical correction clarifying the applicable market basket increase for PPS in each of FYs 2002 and 2003. The technical correction clarifies that the update in home health PPS in FY 2002 and FY 2003 will be the home health market basket minus 1.1 percent.

Section 1895(b)(3)(C) of the Act requires the Secretary to reduce the prospective payment amounts if the Secretary accounts for an addition or adjustment to the payment amount made in the case of outlier payments. The reduction must be in a proportion such that the aggregate reduction in the prospective payment amounts for the given period equals the aggregate increase in payments resulting from the application of outlier payments.

Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix adjustment factor that explains a significant amount of the variation in cost among different units of services. Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services in a geographic area compared to the national average applicable level. These wage-adjustment factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to grant additions or adjustments to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Total outlier payments in a given fiscal year cannot exceed 5 percent of total payments projected or estimated.

Section 1895(b)(6) of the Act provides for the proration of prospective payment amounts between the HHAs involved in the case of a patient electing to transfer or receive services from another HHA within the period covered by the prospective payment amount.

Section 1895(d) of the Act limits review of certain aspects of the HHA PPS. Specifically, there is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following: the establishment of the transition period under 1895(b)(1) of the Act, the definition and application of payment units under section 1895(b)(2) of the Act, the computation of initial standard prospective amounts under 1895(b)(3)(A) of the Act (including the reduction described in section 1895(b)(3)(A)(ii) of the Act), the establishment of the adjustment for outliers under 1895(b)(3)(C) of the Act, the establishment of case-mix and area wage adjustments under 1895(b)(4) of the Act, and the establishment of any adjustments for outliers under 1895(b)(5) of the Act.

Section 4603(b) of the BBA amends section 1815(e)(2) of the Act by eliminating periodic interim payments for HHAs effective October 1, 2000.

Section 4603(c) of the BBA sets forth the following conforming amendments:

- Section 1814(b)(1) of the Act is amended to indicate that payments under Part A will also be made under section 1895 of the Act;
- Section 1833(a)(2)(A) of the Act is amended to require that home health services, other than a covered osteoporosis drug, are paid under HHA PPS;
- Section 1833(a)(2) is amended by adding a new subparagraph (G) regarding payment of Part B services at section 1861(s)(10)(A) of the Act; and
- Section 1842(b)(6)(F) is added to the Act and section 1832(a)(1) of the Act is amended to include a reference to section 1842(b)(6)(F), both governing the consolidated billing requirements.

Section 4603(d) of the BBA was amended by section 5101(c)(2) of OCESAA by changing the effective date language for the HHA PPS and the other changes made by section 4603 of the BBA. Section 4603(d) now provides that: ''Except as otherwise provided, the amendments made by this section shall apply to portions of cost reporting periods occurring on or after October 1, 2000.'' This change requires all HHAs to be paid under HHA PPS effective October 1, 2000 regardless of the current cost-reporting period.

Section 4603(e) of the BBA sets forth the contingency language for HHA PPS noting that if the Secretary, for any reason, does not establish and implement HHA PPS on October 1, 2000, the per-visit cost limits and per-beneficiary limits under the interim payment system will be reduced by 15 percent. Section 302(a) of the BBRA of 1999 eliminated the interim payment system contingency language by striking this section from the statute.

Section 305 of the BBRA refined the consolidated billing requirements under PPS. The new law excludes durable medical equipment (DME) from the home health consolidated billing requirements.

C. Summary of the Proposed Rule

We published a proposed rule in the **Federal Register** on October 28, 1999 at (64 FR 58134) that set forth proposed requirements that would establish the new prospective payment system for home health agencies as required by the Balanced Budget Act (BBA) of 1997, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA), of 1999, and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA). The PPS would replace the retrospective reasonable cost-based system currently used by Medicare for the payment of home health services under Part A and Part B.

1. Transition to PPS

The statute provides authority for a transition period of no longer than 4 years to PPS. We proposed a full transition to the PPS. The overwhelming majority of the industry seems eager to move to PPS. However, some individual home health agencies (HHAs) will object to PPS because they currently enjoy a competitive advantage with high cost limits under the interim payment system. Furthermore, the statute now requires that we pay all providers under PPS on October 1, 2000 rather than phasing in by cost reporting period.

2. Unit of Payment (60-Day Episode)

We proposed a 60-day episode as the basic unit of payment under the HHA PPS. Evidence from the Phase II per-episode HHA PPS demonstration illustrated that the length of a 60-day episode captured a majority of the patients. Moreover, the 60-day episode would coordinate with the 60-day physician recertification of the plan of care and with the 60-day reassessment of the patient using the Outcomes and Assessment Information Set (OASIS). This would encourage physicians' involvement in the plan of care.

3. Split Percentage Payment Approach to the 60-Day Episode Payment (Periodic Interim Payments Statutorily Eliminated With PPS)

Because the PPS system must maintain a cash flow to agencies accustomed to billing on 30-day cycles or receiving periodic interim payments, we proposed a split percentage billing for each 60-day episode. Under this system, an agency would receive a partial episode payment (50 percent) as soon as it notifies us of an admission and a final percentage (50 percent) payment at the close of the 60-day episode.

4. Partial Episode Payment Adjustment (PEP Adjustment)

The partial episode payment adjustment (PEP adjustment) provides a simplified approach to the episode definition and accounts for key intervening events in a patient's care defined as:

—A beneficiary elected transfer, or
—A discharge and return to the same HHA that would warrant a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care before the intervening event. The proportional payment is the PEP adjustment.

The proposed PEP adjustment is based on the span of days including the start-of-care date/first billable service date through and including the last billable service date under the original plan of care before the intervening event. The PEP adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 60. The proportion is multiplied by the original case-mix and wage-adjusted 60-day episode payment.

We also proposed to close out the initial episode payment with a PEP adjustment and restart the 60-day episode clock under an existing episode due to a beneficiary elected transfer. We are concerned that these transfer situations could be subject to manipulation. Therefore, we proposed that we will not apply the PEP adjustment if the transfer is between organizations of common ownership.

In addition, the discharge and return to the same HHA during the 60-day episode period is only recognized when a beneficiary reached the treatment goals in the original plan of care. The original plan of care must be terminated with no anticipated need for additional home health services for the balance of the 60-day period. The discharge cannot be a result of a significant change in condition. In order for the situation to be defined as a PEP adjustment due to discharge and return to the same HHA during the 60-day episode, the discharge must be a termination of the complete course of treatment in the original plan of care. We would not recognize any PEP adjustment in an attempt to circumvent the payment made under the significant change in condition payment adjustment discussed below.

5. Significant Change in Condition Adjustment (SCIC Adjustment)

We proposed that the third intervening event over a course of a 60-day episode of home health care that could trigger a change in payment level to be a significant change in the patient's condition. We proposed the significant change in condition payment adjustment (SCIC adjustment) as the proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode. The proposed SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care.

The SCIC adjustment is calculated in two parts. The first part of the SCIC adjustment reflects the adjustment to the level of payment *before* the significant change in the patient's condition during the 60-day episode. The second part of the SCIC adjustment reflects the adjustment to the level of payment *after* the significant change in the patient's condition occurs during the 60-day episode. The first part of the SCIC adjustment uses the span of days of the first billable service date through the last billable service date before the intervening event of the patient's significant change in condition that warrants a new case-mix assignment for payment. The first part of the SCIC adjustment is determined by taking the span of days before the patient's significant change in condition as a proportion of 60 multiplied by the original episode payment amount. The original episode payment level is proportionally adjusted using the span of time the patient was under the care of the HHA before the significant change in condition that warranted an OASIS assessment, physician change orders indicating the need for a significant change in the course of the treatment plan, and the new case-mix assignment for payment at the end of the 60-day episode.

The second part of the SCIC adjustment reflects the time the patient is under the care of the HHA after the patient experienced the significant change in condition during the 60-day episode that warranted the new case-mix assignment for payment purposes. The second part of the SCIC adjustment is a proportional payment adjustment reflecting the time the patient will be under the care of the HHA after the significant change in condition and continuing until the end of the 60-day episode. Once the HHA completes the OASIS, obtains the necessary physician change orders reflecting the need for a new course of treatment in the plan of care, and assigns a new case-mix level for payment, the second part of the SCIC adjustment begins. The second part of the SCIC adjustment is determined by taking the span of days (first billable service date through the last billable service date) after the patient experiences the significant change in condition through the balance of the 60-day episode as a proportion of 60 multiplied by the new episode payment level resulting from the significant change. The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second parts of the SCIC adjustment (or any applicable medical review or low utilization payment adjustment (LUPA) discussed below) determined at the final billing for the 60-day episode.

6. Low-Utilization Payment Adjustment (LUPA)

We proposed payments for low-utilization episodes by paying those episodes at a standardized average per-visit amount. Episodes with four or fewer visits would be paid the per-visit amount times the number of visits actually provided during the episode. ''Savings'' from reduced episode payments would be redistributed to all episodes.

7. Case-Mix Methodology

In the proposed rule, we described a home health case-mix system developed under a research contract with Abt Associates, Inc., of Cambridge, Massachusetts. The case-mix system uses selected data elements from the OASIS assessment instrument and an additional data element measuring receipt of therapy services of at least 8 hours (the 8-hour threshold has been defined as 10 visits for purposes of case-mix adjustment of PPS reimbursements). The data elements are organized into three dimensions to capture clinical severity factors, functional severity factors, and services utilization factors influencing case-mix. The process of selecting data elements for each dimension was described in the proposed rule. In the clinical and functional dimensions, each data element is assigned a score value derived from multiple regression analysis of the Abt research data. The score value measures the impact of the data element on total resource use. Scores are also assigned to data elements in the services utilization dimension. To find a patient's case-mix group, the case-mix grouper sums the patient's scores within each of the three dimensions. The resulting sum is used to assign the patient to a severity level on each dimension. There are four clinical severity levels, five functional severity levels, and four services utilization severity levels. Thus there are 80 possible combinations of severity levels across the three dimensions. Each combination defines one of the 80 groups in the case-mix system. For example, a patient with high clinical severity, moderate functional severity, and low services utilization severity is placed in the same group with all other patients whose summed scores place them in the same set of severity levels for the three dimensions.

8. Outlier Payments

Outlier payments are payments made in addition to the 60-day episode payments for episodes that incur unusually large costs. Outlier payments would be made for episodes whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group, PEP adjustment or total SCIC adjustment would be the episode payment amount, PEP adjustment, or total SCIC adjustment for that group plus a fixed dollar loss amount that is the same for all case-mix groups. The outlier payment would be a proportion of the amount of estimated costs beyond the threshold. Costs would be estimated for each episode by applying standard per-visit amounts to the number of visits by discipline reported on claims. The fixed dollar loss amount and the loss-sharing proportion are chosen so that total outlier payments are estimated to be no more than 5 percent of estimated total payments. There is no need for a long-stay outlier payment because we would not be limiting the number of continuous episode payments in a fiscal year that may be made for Medicare covered home health care to eligible beneficiaries.

9. Consolidated Billing/Bundling

Under the consolidated billing requirement, we would require that the HHA submit all Medicare claims for the home health services included in 1861(m) of the Social Security Act while the beneficiary is under the home health plan of care established by a physician and is eligible for the home health benefit. The proposed rule included an approach that was superseded by changes to the law made by the BBRA.

II. Provisions of Proposed Rule

In the proposed rule that was published on October 28, 1999 (64 FR 54134), we proposed a number of revisions to the regulations in order to implement the prospective payment system, the HHA consolidated billing provision, and conforming statutory changes. We proposed to make conforming changes in 42 CFR parts 409, 424, and 484 to synchronize all timeframes for the plan of care certification, OASIS Recertification (follow-up) assessment, and episode payments to reflect a 60-day period. In addition, we proposed to add a new subpart in part 484 to set forth our new payment system for HHAs. These revisions and others are discussed in detail below.

First, we proposed to revise part 409, subpart E, and discussed the requirements that must be met for Medicare to make payment for home health services. We proposed to make a conforming change in § 409.43 regarding the plan of care requirements. Specifically, we proposed to revise the frequency for review in paragraph (e) of this section by replacing the phrase ''62 days'' with ''60 days unless there is—

- An intervening beneficiary elected transfer;
- A significant change in condition resulting in a new case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode that warrants a new 60-day episode payment and a new physician certification of the new plan of care.

In addition, we proposed to revise subpart H of this part regarding payments of hospital insurance benefits. We proposed to revise paragraph (a) in § 409.100, which discusses payment for services, to specify the conditions under which Medicare may pay hospital insurance benefits for home health services. We proposed to provide introductory text to paragraph (a) and to redesignate the current paragraph (a) as paragraph (a)(1). Proposed paragraph (a)(2) of this section would require that Medicare may pay hospital insurance benefits for the home health services specified at section 1861(m) of the Act, when furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

We proposed to make similar changes in part 410, subpart I, which deals with payment of benefits under Part B. We proposed to add a new paragraph (b)(19) to § 410.150 to specify the conditions under which Medicare Part B pays for home health services. Specifically, proposed paragraph (b)(19) specified that Medicare Part B pay a participating HHA, for home health services furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

We also proposed to revise part 411 subpart A, which discusses excluded services. We proposed to add a new paragraph (q) to § 411.15 to specify the conditions under which HHA services are excluded from coverage. Proposed paragraph (q) specified that a home health service as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA is excluded from coverage unless that HHA has submitted a claim for payment for such services.

We also proposed to simplify the authority citation for part 413. In § 413.1 in the introduction to the section on principles of reasonable cost reimbursement, we proposed to add a new paragraph (h) to include the timeframe under which home health services will be paid prospectively. Paragraph (h) under this section specified that the amount paid for home health services as defined in section 1861(m) of the Act that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter. In addition, we proposed to amend § 413.64 concerning payments to providers. Specifically, we proposed to amend paragraph (h)(1) of this section by removing Part A and Part B HHA services from the periodic interim payment method.

We also proposed to revise part 424, which explains the conditions for Medicare payment. We proposed to revise § 424.22 regarding the certification requirements as a condition for payment. We proposed to add a new paragraph (a)(1)(v) that would specify that as a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify that the individual is correctly assigned to one of the HHRGs. We proposed to make a conforming change at paragraph (b)(1) of this section regarding the timing of the recertification. Specifically, we proposed to amend § 424.22(b) by replacing the phrase ''at least every 2 months'' with ''at least every 60 days,'' and adding the following sentence: ''Recertification is required at least every 60 days preferably unless there is a beneficiary elected transfer, a significant change in condition resulting in a new case-mix assignment, or a discharge and return to the same HHA during the 60-day episode that warrants a new 60-day episode payment and a new physician certification of the new plan of care.''

We proposed to add a new statutory authority, section 1895 of the Act, to paragraph(a) of § 484.200, ''Basis and scope.'' Section 1895(a) provides for the implementation of a prospective payment system for HHAs for portions of cost-reporting periods occurring on or after October 1, 2000.

We proposed to revise the regulations in 42 CFR part 484, which set forth the conditions that an HHA must meet in order to participate in Medicare. First, we proposed to revise the part heading from ''Conditions Of Participation: Home Health Agencies'' to the more generic heading ''Home Health Services.'' We proposed to make a conforming change in § 484.18(b) by replacing the phrase ''62 days'' with ''60 days'' unless there is—

- A beneficiary elected transfer;
- A significant change in condition resulting in a change in the case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode.

Also, we proposed to revise § 484.55(d)(1) by replacing ''every second calendar month'' with language that reflects the 60-day episode and possible PEP Adjustment or SCIC Adjustment. We proposed to require that the comprehensive assessment be updated and revised as frequently as the patient's condition warrants but not less frequently than every 60 days beginning with the start-of-care date unless there is—

- A beneficiary elected transfer;
- A significant change in condition resulting in a change in the case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode.

In addition, we proposed to add and reserve a new subpart D, then add a new subpart E, ''Prospective Payment System for Home Health Agencies.'' This proposed subpart sets forth the regulatory framework of the new prospective payment system. It specifically discussed the development of the payment rates, associated adjustments, and related rules. In § 484.202, ''Definitions,'' we proposed the following definitions for purposes of this new subpart:

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Clinical model means a system for classifying Medicare-eligible patients under a home health plan of care into mutually exclusive groups based on clinical, functional, and intensity-of-service criteria. The mutually exclusive groups are defined as Home Health Resource Groups (HHRGs).

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

In proposed § 484.205 ''Basis of payment,'' we discussed the Medicare payment to providers of services. Proposed § 484.205(a) described the method by which the provider would receive payment. Specifically, § 484.205(a)(1) provided that an HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis. We determine this national 60-day episode payment under the methodology set forth in § 484.215. Paragraph (a)(2) specified that an HHA may receive a low-utilization payment adjustment (LUPA) of a predetermined per-visit rate. We proposed to determine the LUPA under the methodology set forth in § 484.230. Paragraph (a)(3) of this section provided that an HHA may receive a partial episode payment (PEP) adjustment due to an intervening event during an existing 60-day episode that initiates the start of a new 60-day episode payment and a new patient plan of care. We proposed to determine the PEP Adjustment under the methodology set forth in § 484.235. Paragraph (a)(4) of this section specified that a HHA may receive a significant change in condition (SCIC) Adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. We proposed to determine the SCIC adjustment under a methodology set forth in 484.237.

Proposed paragraph (b) discussed the 60-day episode payment and circumstances surrounding adjustments to the payment method. This paragraph proposed that the national 60-day episode payment represents payment in full for all costs associated with furnishing a home health service paid on a reasonable cost basis as of August 5, 1997 (the date of the enactment of the BBA) unless the national 60-day episode payment is subject to a low-utilization payment adjustment as set forth in § 484.230, a partial episode payment adjustment as set forth in § 484.235, a significant change in condition payment adjustment as set forth in 484.237, or an additional outlier payment as set forth in § 484.240. All payments under this system may be subject to a medical review adjustment. We noted that DME provided as a home health service as defined in section 1861(m) of the Act would continue to be paid the fee schedule amount.

In paragraph (c) of this section, we proposed the low-utilization payment adjustment to the 60-day episode payment. We would require that an HHA receive a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless we determine at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. The low-utilization payment adjustment would be determined under the methodology set forth in § 484.230.

In paragraph (d), we discussed the partial episode payment adjustment. We describe that an HHA receives a national payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless there is an intervening event that warrants the initiation of a new 60-day episode payment and a new physician certification of the new plan of care. The initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care. A partial episode payment adjustment would be determined under the methodology set forth in § 484.235.

In paragraph (e), we discussed the significant change in condition adjustment. We discussed that the HHA receives a national 60-day episode payment of a pre-determined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines an intervening event defined as a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient's plan of care. The significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode.

In paragraph (f), we discussed how we treat payment for outliers. In this paragraph we would provide that an HHA receives a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable-cost basis as of August 5, 1997, unless the estimated cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the estimated costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment would be determined under the methodology set forth in § 484.240.

In proposed § 484.210, we specified the data used for the calculation of the national prospective 60-day episode payment. These data include the following:

- Medicare cost data on the most recent audited cost report data available.
- Utilization data based on Medicare claims.
- An appropriate wage index to adjust for area wage differences.
- The most recent projections of increases in costs from the HHA market basket index.
- OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix.

Proposed § 484.215, paragraphs (a) through (e) specified the methodology used for the calculation of the national 60-day episode payment. Proposed paragraph (a) specified that in calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, we determined each HHA's costs by summing its allowable costs for the period. We then determined the national mean cost per visit.

Proposed paragraph (b) of this section specified that in calculating the initial unadjusted national 60-day episode payment, we determined the national mean utilization for each of the six disciplines using home health claims data.

Proposed paragraph (c) of this section specified that we used the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001. For each fiscal year from 2002 or 2003, we would update the cost data by a factor equivalent to the annual market basket index percentage minus 1.1 percentage points.

Proposed paragraph (d) regarding standardization of the data for variation in area wage levels and case-mix specified that we would standardize the cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix. We would then standardize the cost data for geographic variation in wage levels using the hospital wage index. We standardized the cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

Proposed paragraph (e) of this section described how we calculated the unadjusted national average prospective payment amount for the 60-day episode. Specifically, we calculated this payment amount by—

- Computing the mean standardized national cost per visit;
- Computing the national mean utilization for each discipline; then
- Multiplying the mean standardized national cost per visit by the national mean utilization summed in the aggregate for each discipline.

Proposed § 484.220 described how we calculated the national adjusted prospective 60-day episode payment rate for case-mix and area wage levels. This section specified that we adjusted the national prospective 60-day episode payment rate to account for HHA case-mix using a case-mix index to explain the relative resource utilization of different patients. We also adjusted the national prospective 60-day episode payment rate to account for geographic differences in wage levels using an appropriate wage index.

In proposed § 484.225, we explained our methods for annually updating the national adjusted prospective payment rates for inflation. We proposed to handle it in the following manner:

- We update the unadjusted national 60-day episode payment rate on a fiscal year basis.
- For FY 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available market basket factors.
- For fiscal year 2002 or 2003, the unadjusted national 60-day episode payment rate is equal to the rate for the previous period or fiscal year increased

by a factor equal to the HHA market basket minus 1.1 percentage point.

• For any subsequent fiscal years, the unadjusted national rate is equal to the rate for the previous fiscal year increased by the applicable HHA market basket index amount.

In proposed § 484.230, we explained the methodology we use for the calculation of the low-utilization payment adjustment. In this section, we specified that in calculating the low-utilization payment adjustment, an episode with four or fewer visits is paid the national average standardized per-visit amount by discipline for each visit type. We also specified that the national average standardized per-visit amount is determined by using cost data set forth in § 484.210(a) and adjusting by the appropriate wage index.

Proposed § 484.235 illustrated the methodology we used to calculate the partial episode payment adjustment. The intervening event of either a beneficiary elected transfer or discharge and return to the same HHA during the 60-day episode warrants a new 60-day episode payment and a new physician certification of a new plan of care. The original 60-day episode payment is adjusted with a partial episode payment that reflects the length of time the beneficiary remained under the care of the original HHA. The partial episode payment is calculated using the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

Proposed 484.237 illustrated the methodology we used to calculate the significant change in condition payment adjustment. The intervening event, here, a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care, initiates the significant change in condition payment adjustment. The significant change in condition is calculated in two parts. The first part of the SCIC adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The second part of the SCIC adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount. The original episode payment level is proportionally adjusted using the span of time the patient was under the care of the HHA prior to the significant change in condition that warranted an OASIS assessment, physician change orders indicating the need for a significant change in the course of the treatment plan, and the new case-mix assignment for payment at the end of the 60-day episode. The second part of the SCIC adjustment is a proportional payment adjustment reflecting the time the patient will be under the care of the HHA after the significant change in condition and continuing until the end of the 60-day episode. The second part of the SCIC adjustment is determined by taking the span of days (first billable visit date through the last billable visit date) after the patient experiences the significant change in condition through the balance of the 60-day episode as a proportion of 60 multiplied by the new episode payment level resulting from the significant change. The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second part of the SCIC adjustment.

Proposed § 484.240 described the methodology we used to calculate the outlier payment. The methodology for the calculation of the outlier payment would involve the following:

• We make an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

• The outlier threshold for each case-mix group is the episode payment amount for that group plus a fixed dollar loss amount that is the same for all case-mix groups.

• The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

• We estimate the cost for each episode by applying the standard per-visit amount to the number of visits by discipline reported on claims.

• The fixed dollar loss amount and the loss-sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total episode payment.

Proposed § 484.250 related to data that must be submitted for the development of a reliable case-mix. Specifically, we would require an HHA to submit the OASIS data described at the current § 484.55(b)(1) and (d)(1) (that we proposed to revise in the proposed rule) to administer the payment rate methodologies described in § 484.215 (methodology used for the calculation of the national 60-day episode payment), § 484.230 (methodology used for the calculation of the LUPA) and 484.237 (methodology used for the calculation of the SCIC adjustment).

Proposed § 484.260 discussed the limitation for review with regard to our new payment system. In this section, we specified that judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of a payment unit including the national 60-day episode payment rate and the LUPA. This prohibition includes the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

III. Analysis and Responses to Public Comments

We received approximately 381 timely comments on the HHA prospective payment system proposed rule HCFA–1059–P published on October 28, 1999 (64 FR 58134). Comments were submitted by HHAs and other health care providers, national industry associations, suppliers and practitioners (both individually and through their respective trade associations), State associations, health care consulting firms, and private citizens. The comments centered on various aspects of the proposed policies governing our approach to the home health prospective payment system. We have considered all comments received during the 60-day public comment period in this final rule and have set forth our responses to the comments and corresponding policy modifications in the following section.

As noted in the proposed rule, because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to respond to them individually. In particular, a number of commenters on the proposed rule raised extremely technical and detailed questions, many of which were not directly related to the proposed rule, regarding OASIS, the cost report, RHHI systems and the billing process. These questions are of the nature that would more appropriately be addressed through manual instructions and other issuances than in these regulations. In this final rule, we are addressing the policy concerns raised by the commenters that are related to the proposed rule. Summaries of the major issues and our responses to those comments are set forth below.

A. 60-Day Episode Payment Definition (§ 484.205)

Comment: We received several comments on our proposed definition of a 60-day episode as the unit of payment under HHA PPS. The majority of commenters supported the 60-day episode approach. A few commenters suggested a shorter time period for the unit of payment.

Response: We believe the 60-day episode definition is the most appropriate approach to define the unit of payment under HHA PPS. Public support for the 60-day episode as the unit of payment under PPS centered on the general consensus that HHAs and physicians predict home care needs over a 60-day period due to current plan of care requirements and OASIS assessments that basically follow a 60-day period. As discussed in detail in the proposed rule, research indicated that the 60-day episode captures the majority of stays experienced in the Phase II per-episode HHA PPS demonstration.

We will continue to monitor the appropriateness of the 60-day unit of payment and may consider modifying our approach to the episode definition in subsequent years of PPS, if warranted.

Comment: A few commenters raised concerns with the change to a 60-day episode from the current plan of care certification and OASIS assessments requirements that follow a bimonthly period, that is, at least every 62 days. Some of the concerns centered on confusion and the possible burden associated with the change to a 60-day episode.

Response: The statute requires us to establish an appropriate unit of payment. We believe the 60-day episode is the most suitable time frame upon which to base payment and to manage home care needs of patients. To effectively implement a payment system that is built on a foundation of (1) OASIS assessments for case-mix adjustment and (2) plan of care certifications to ensure the appropriate plan of treatment, all schedules for assessment, certification and payment term should be on a parallel track. The current schedules for OASIS assessment and plan of care certification basically mirror a 60-day episode. Thus, for purposes of payment, assessment, and care planning, we do not believe it is an undue burden to adjust to a 60-day episode from a bimonthly period.

Comment: A few commenters recommended that we re-examine the language we proposed to govern the 60-day episode. The commenters referred specifically to the following statement in the proposed rule: ‘‘An HHA that accepts a Medicare eligible beneficiary for home health care for the 60-day episode period and submits a bill for payment may not refuse to treat an eligible beneficiary who has been discharged from the HHA during the 60-day episode, but later requires Medicare covered home health services during the same 60-day episode period and elects to return to the same HHA * * *’’ (64 FR 58201) Commenters suggested that HHAs should be allowed to refuse to readmit a Medicare eligible beneficiary in accordance with HHA policies when the safety of HHA staff or the patient are threatened; when the HHA does not have the staff necessary to meet the patient’s needs; or when the patient or caregiver refuses to cooperate or comply with the plan of care.

Response: We proposed this policy to indicate that we would not accept a refusal to treat the beneficiary when only the HHA’s economic interests were the cause of the refusal. It was not our intent to restrict the legitimate rights of an HHA that has a well-documented individualized situation that results in a determination to refuse further care of a patient. This would include threats to the safety of HHA staff or patients or failure of patients to cooperate in the care plan. As long as agencies treat all similarly situated patients equally, document the individualized situation, and comply with all Federal and State laws, they have the right to refuse to treat patients in certain well-documented situations.

B. Definition of Non-Routine Medical Supplies Included in the Episode Definition

Comment: We received several comments regarding certain non-routine medical supply costs that were not included in the computation of the 60-day national episode rate. Specifically, the commenters suggested that we include non-routine medical supplies both paid on the cost report and non-routine medical supply amounts that could have been unbundled to part B prior to PPS in the 60-day episode rate. Commenters also provided several suggestions for a revised approach to the payment for non-routine medical supplies under HHA PPS. Recommendations included the following:

- Providing for a separate payment for non-routine medical supplies used by a patient designated as a new designated home health supply payment amount separate from the prospective payment rate.
- Allowing all non-routine medical supplies to be billed under Part B.
- Carving out or adjusting the medical supply amount due to the variation in intermediary coverage guidelines.
- Adjusting the medical supply amounts to reflect the costs associated with wound patients, chux and diaper supply patients.
- Paying medical supplies as used because of the wide variation in use due to patients who sustain out-of-pocket payments.
- Carving out wound care and diabetes related medical supplies and re-examining the overall calculation of the non-routine supply costs, both bundled and non-routine supply costs that could have been unbundled, because commenters viewed the amounts inadequate to care for patients requiring supplies which then might lead to access issues.

Commenters further noted problems with the 199 HCPCs codes we used to calculate the non-routine medical supply amounts that could have been unbundled to Part B before implementation of PPS. We adjusted the proposed rate to account for the non-routine medical supply behavior prior to PPS. Several commenters suggested that the inclusion of glucose test strips codes were inappropriate codes included in the original 199 code list for non-routine medical supply costs. Other commenters believed we inadvertently omitted certain codes in the original list of 199 codes. Furthermore, several commenters centered on consolidated billing requirements for non-routine medical supplies. We note that all consolidated billing comments and responses are included under the consolidated billing portion of this section of the regulation.

Response: The goal of reviewing and calculating the non-routine medical supply costs that could have been unbundled to Part B was to ensure adequate payment for non-routine medical supplies used by a patient under a home health plan of care in the prospective payment rate. As stated in the proposed rule, we developed a list of 199 codes that could have possibly been unbundled to Part B before implementation of PPS, linked those Part B supply claims that included any of the 199 codes to home health claims for beneficiaries under a home health plan of care during calendar year 1997. We have replicated the exact claims analysis on corresponding calendar year 1998 claims data to develop an updated supply amount for this final regulation. This calculation was performed on an adjusted list of codes based upon review of comments and is described below.

As stated in the proposed rule, section 1895(b)(1) of the Act, which governs the development of the unit of payment under HHA PPS, requires all services covered and paid on a reasonable cost basis as of the date of enactment of the BBA, including medical supplies, to be paid on the basis of a prospective payment amount under HHA PPS. The statutory language specifically refers to the inclusion of medical supplies in the prospective payment rate. We believe the statute requires the inclusion of costs of non-routine medical supplies in the episode rate. However, as stated in the proposed rule, since DME covered as a home health service as part of the Medicare home health benefit is not currently paid on a reasonable cost basis, DME will continue to be paid under the DME fee schedule as a separate payment amount from the prospective payment rates under HHA PPS.

As mentioned above, commenters also supplied us with an additional 79 codes that they believed should be included on our list of non-routine medical supplies that could have been unbundled to Part B. We re-examined our approach to the original 199 codes used to calculate the amounts that could have been unbundled non-routine medical supplies. We found that several of the recommended codes had been discontinued. Further, upon re-examination of our original list, we found that several of the original codes were inappropriately included, for example, glucose test strips. These codes have subsequently been deleted. Our analysis results in a final list of 178 codes as listed below. We have provided the following analysis in order to clarify our revised approach.

59 codes proposed in comments were discontinued codes as of 12/31/96.

A4190	Transparent film each
A4200	Gauze pad medicated/non-med
A4202	Elastic gauze roll
A4203	Non-elastic gauze roll
A4204	Absorptive drsg
A4205	Nonabsorptive drsg
K0197	Alginate drsg > 16 <=48 sq in
K0198	Alginate drsg > 48 sq in
K0199	Alginate drsg wound filler
K0203	Composite drsg <= 16 sq in
K0204	Composite drsg > 16 <=48 sq in
K0205	Composite drsg > 48 sq in
K0206	Contact layer <= 16 sq in
K0207	Contact layer > 16 <= 48 sq in
K0208	Contact layer > 48 sq in
K0209	Foam drg <= 16 sq in w/o bdr
K0210	Foam drg > 16 <=48 sq in w/o b
K0211	Foam drg > 48 sq in w/o brdr
K0212	Foam drg <= 16 sq in w/bdr
K0213	Foam drg > 16 <=48 sq in w/ bdr
K0214	Foam drg > 48 sq in w/bdr
K0215	Foam dressing wound filler
K0219	Gauze <= 16 sq in w/bdr
K0220	Gauze > 16 <=48 sq in w/bdr
K0221	Gauze > 48 sq in w/bdr
K0222	Gauze <= 16 in no w/sal w/o b
K0223	Gauze > 16 <=48 no w/sal w/o b
K0224	Gauze > 48 in no w/sal w/o b
K0228	Gauze <= 16 sq in water/sal
K0229	Gauze > 16 <=48 sq in watr/sal
K0230	Gauze > 48 sq in water/salne
K0234	Hydrocolloid drg <= 16 w/o bdr
K0235	Hydrocolloid drg > 16 <=48 w/o b
K0236	Hydrocolloid drg > 48 in w/o b
K0237	Hydrocolloid drg <= 16 in w/ bdr
K0238	Hydrocolloid drg > 16 <=48 w/ bdr
K0239	Hydrocolloid drg > 48 in w/bdr
K0240	Hydrocolloid drg filler paste
K0241	Hydrocolloid drg filler dry
K0242	Hydrogel drg <= 16 in w/o bdr
K0243	Hydrogel drg > 16 <=48 w/o bdr
K0244	Hydrogel drg > 48 in w/o bdr
K0245	Hydrogel drg <= 16 in w/bdr
K0246	Hydrogel drg > 16 <=48 in w/b
K0247	Hydrogel drg > 48 sq in w/b
K0248	Hydrogel drsg gel filler
K0249	Hydrogel drsg dry filler
K0251	Absorpt drg <= 16 sq in w/o b
K0252	Absorpt drg > 16 <=48 w/o bdr
K0253	Absorpt drg > 48 sq in w/o b
K0254	Absorpt drg <= 16 sq in w/bdr
K0255	Absorpt drg > 16 <=48 in w/ bdr
K0256	Absorpt drg > 48 sq in w/bdr
K0257	Transparent film <= 16 sq in
K0258	Transparent film > 16 <=48 in
K0259	Transplant filmpercent 48 sq in
K0261	Wound filler gel/paste/oz
K0262	Wound filler dry form/gram
K0266	Impreg gauze no h20/sal/yard

Seven codes included in original list should be removed because they are considered routine medical supplies and as such would not be separately billable by an HHA.

A4214	30 CC sterile water/saline
K0216	Non-sterile gauze <= 16 sq in
K0217	Non-sterile gauze > 16 <= 48 sq
K0218	Non-sterile gauze > 48 sq in
K0263	Non-sterile elastic gauze/yd
K0264	Non-sterile no elastic gauze
K0265	Tape per 18 sq inches

Four codes are not valid for Medicare.

A4206	1 CC sterile syringe & needle
A4207	2 CC sterile syringe & needle
A4208	3 CC sterile syringe & needle
A4209	5+ CC sterile syringe & needle

Three codes are for items that are not covered under Medicare.

A4210.	Nonneedle injection device
K0250	Skin seal protect moisturizer
K0260	Wound cleanser any type/size

One code is a DME Fee Schedule code and should not be included in accordance with the statute.

A4221	Maint drug infus cath per wk

One code is not separately paid by Part B.

A4211	Supp for self-adm injections

Three codes mentioned by commenters had already been included in our original list of 199 codes.

A4212	Non coring needle or stylet
A4213	20+ CC syringe only
A4215	Sterile needle

After further re-examination based upon the comments, we added the following code to the list:

A4554	Disposable underpads

Upon further review of the original 199 codes used in the proposed rule, the following codes were deemed inappropriate to be included in the definition of non-routine medical supplies and were deleted from the list used in this final rule:

A4206	1 CC sterile syringe & needle
A4207	2 CC sterile syringe & needle
A4208	3 CC sterile syringe & needle
A4209	5+ CC sterile syringe & needle
A4210	Nonneedle injection device
A4211	Supp for self-adm injections
A4214	30 CC sterile water/saline
A4253	Blood glucose/reagent strips
A4255	Glucose monitor platforms
A4256	Calibrator solution/chips
A4258	Lancet device each
A4259	Lancets per box
A4454	Tape all types all sizes
A6216	Non-sterile gauze <= 16 sq in
A6217	Non-sterile gauze > 16 <= 48 sq
A6218	Non-sterile gauze > 48 sq in
A6263	Non-sterile elastic gauze/yd
A6264	Non-sterile no elastic gauze
A6265	Tape per 18 sq inches
K0137	Skin barrier liquid per oz
K0138	Skin barrier paste per oz
K0139	Skin barrier powder per oz

The following is the *final* list of *178* codes for non- Routine Medical Supplies that have a duplicate Part B code that could have been unbundled and billed under Part B before implementation of PPS. The following codes were used to calculate additional non-routine medical supply costs to the national rate. The revised rate calculation is found in section IV.C. of this preamble.

A4212	Non coring needle or stylet
A4213	20+ CC syringe only
A4215	Sterile needle
A4310	Insert tray w/o bag/cath
A4311	Catheter w/o bag 2-way latex
A4312	Cath w/o bag 2-way silicone
A4313	Catheter w/bag 3-way
A4314	Cath w/drainage 2-way latex
A4315	Cath w/drainage 2-way silcne
A4316	Cath w/drainage 3-way
A4320	Irrigation tray
A4321	Cath therapeutic irrig agent
A4322	Irrigation syringe
A4323	Saline irrigation solution
A4326	Male external catheter
A4327	Fem urinary collect dev cup
A4328	Fem urinary collect pouch
A4329	External catheter start set
A4330	Stool collection pouch
A4335	Incontinence supply
A4338	Indwelling catheter latex
A4340	Indwelling catheter special
A4344	Cath indw foley 2 way silicn
A4346	Cath indw foley 3 way

A4347	Male external catheter
A4351	Straight tip urine catheter
A4352	Coude tip urinary catheter
A4353	Intermittent urinary cath
A4354	Cath insertion tray w/bag
A4355	Bladder irrigation tubing
A4356	Ext ureth clmp or compr dvc
A4357	Bedside drainage bag
A4358	Urinary leg bag
A4359	Urinary suspensory w/o leg bag
A4361	Ostomy face plate
A4362	Solid skin barrier
A4363	Liquid skin barrier
A4364	Ostomy/cath adhesive
A4365	Ostomy adhesive remover wipe
A4367	Ostomy belt
A4368	Ostomy filter
A4397	Irrigation supply sleeve
A4398	Ostomy irrigation bag
A4399	Ostomy irrig cone/cath w brs
A4400	Ostomy irrigation set
A4402	Lubricant per ounce
A4404	Ostomy ring each
A4421	Ostomy supply misc
A4454	Tape all types all sizes
A4455	Adhesive remover per ounce
A4460	Elastic compression bandage
A4462	Abdmnl drssng holder/binder
A4481	Tracheostoma filter
A4622	Tracheostomy or larngectomy
A4623	Tracheostomy inner cannula
A4625	Trach care kit for new trach
A4626	Tracheostomy cleaning brush
A4649	Surgical supplies
A5051	Pouch clsd w barr attached
A5052	Clsd ostomy pouch w/o barr
A5053	Clsd ostomy pouch faceplate
A5054	Clsd ostomy pouch w/flange
A5055	Stoma cap
A5061	Pouch drainable w barrier at
A5062	Drnble ostomy pouch w/o barr
A5063	Drain ostomy pouch w/flange
A5071	Urinary pouch w/barrier
A5072	Urinary pouch w/o barrier
A5073	Urinary pouch on barr w/flng
A5081	Continent stoma plug
A5082	Continent stoma catheter
A5093	Ostomy accessory convex inse
A5102	Bedside drain btl w/wo tube
A5105	Urinary suspensory
A5112	Urinary leg bag
A5113	Latex leg strap
A5114	Foam/fabric leg strap
A5119	Skin barrier wipes box pr 50
A5121	Solid skin barrier 6x6
A5122	Solid skin barrier 8x8
A5123	Skin barrier with flange
A5126	Disk/foam pad +or− adhesive
A5131	Appliance cleaner
A5149	Incontinence/ostomy supply
A6020	Collagen wound dressing
A6154	Wound pouch each
A6196	Alginate dressing <= 16 sq in
A6197	Alginate drsg > 16 <= 48 sq in
A6198	Alginate dressing > 48 sq in
A6199	Alginate drsg wound filler
A6200	Compos drsg <= 16 no bdr
A6201	Compos drsg > 16 <=48 no bdr
A6202	Compos drsg > 48 no bdr
A6203	Composite drsg <= 16 sq in
A6204	Composite drsg > 16 <=48 sq in
A6205	Composite drsg > 48 sq in
A6206	Contact layer <= 16 sq in
A6207	Contact layer > 16 <= 48 sq in
A6208	Contact layer > 48 sq in
A6209	Foam drsg <= 16 sq in w/o bdr
A6210	Foam drg > 16 <=48 sq in w/o b
A6211	Foam drg > 48 sq in w/o brdr
A6212	Foam drg <= 16 sq in w/bdr
A6213	Foam drg > 16 <=48 sq in w/ bdr
A6214	Foam drg > 48 sq in w/bdr
A6215	Foam dressing wound filler
A6219	Gauze <= 16 sq in w/bdr
A6220	Gauze > 16 <=48 sq in w/bdr
A6221	Gauze > 48 sq in w/bdr
A6222	Gauze <= 16 in no w/sal w/o b
A6223	Gauze > 16 <= 48 no w/sal w/o b
A6224	Gauze > 48 in no w/sal w/o b
A6228	Gauze <= 16 sq in water/sal
A6229	Gauze > 16 <=48 sq in watr/sal
A6230	Gauze > 48 sq in water/salne
A6234	Hydrocolld drg <= 16 w/o bdr
A6235	Hydrocolld drg > 16 <= 48 w/o b
A6236	Hydrocolld drg > 48 in w/o b
A6237	Hydrocolld drg <= 16 in w/bdr
A6238	Hydrocolld drg > 16 <=48 w/ bdr
A6239	Hydrocolld drg > 48 in w/bdr
A6240	Hydrocolld drg filler paste
A6241	Hydrocolloid drg filler dry
A6242	Hydrogel drg <= 16 in w/o bdr
A6243	Hydrogel drg > 16 <=48 w/o bdr
A6244	Hydrogel drg > 48 in w/o bdr
A6245	Hydrogel drg <= 16 in w/bdr
A6246	Hydrogel drg > 16 <=48 in w/b
A6247	Hydrogel drg > 48 sq in w/b
A6251	Absorpt drg <= 16 sq in w/o b
A6252	Absorpt drg > 16 <=48 w/o bdr
A6253	Absorpt drg > 48 sq in w/o b
A6254	Absorpt drg <= 16 sq in w/bdr
A6255	Absorpt drg > 16 <=48 in w/ bdr
A6256	Absorpt drg > 48 sq in w/bdr
A6257	Transparent film <= 16 sq in
A6258	Transparent film > 16 <=48 in
A6259	Transparent film > 48 sq in
A6261	Wound filler gel/paste/oz
A6262	Wound filler dry form/gram
A6266	Impreg gauze no h20/sal/yard
A6402	Sterile gauze <= 16 sq in
A6403	Sterile gauze > 16 <= 48 sq in
A6404	Sterile gauze > 48 sq in
A6405	Sterile elastic gauze/yd
A6406	Sterile non-elastic gauze/yd
K0137	Skin barrier liquid per oz
K0138	Skin barrier paste per oz
K0139	Skin barrier powder per oz
K0277	Skin barrier solid 4x4 equiv
K0278	Skin barrier with flange
K0279	Skin barrier extended wear
K0280	Extension drainage tubing
K0281	Lubricant catheter insertion
K0407	Urinary cath skin attachment
K0408	Urinary cath leg strap
K0409	Sterile H2O irrigation solut
K0410	Male ext cath w/adh coating
K0411	Male ext cath w/adh strip
K0419	Drainable plstic pch w fcplt
K0420	Drainable rubber pch w fcplt
K0421	drainable plstic pch w/o fp
K0422	Drainable rubber pch w/o fp
K0423	Urinary plstic pouch w fcplt
K0424	Urinary rubber pouch w fcplt
K0425	Urinary plstic pouch w/o fp
K0426	Urinary hvy plstc pch w/o fp
K0427	Urinary rubber pouch w/o fp
K0428	Ostomy faceplt/silicone ring
K0429	Skin barrier solid ext wear
K0430	Skin barrier w flang ex wear
K0431	Closed pouch w st wear bar
K0432	Drainable pch w ex wear bar
K0433	Drainable pch w st wear bar
K0434	Drainable pch ex wear convex
K0435	Urinary pouch w ex wear bar
K0436	Urinary pouch w st wear bar
K0437	Urine pch w ex wear bar conv
K0438	Ostomy pouch liq deodorant
K0439	Ostomy pouch solid deodorant

We believe our revised approach to the calculation that incorporates both non-routine medical supplies provided under a plan of care and those non-routine medical supplies that could have been unbundled to Part B prior to the consolidated billing requirements results in an equitable payment methodology. As stated above, we have re-examined the list of non-routine medical supplies that could have been unbundled to Part B, recalculated the costs, and have adjusted the rates accordingly. We have also included any additional medical supply costs included in the audited cost report data from the sample that became available after the publication of the proposed rule.

We have thoroughly re-examined the issue of all non-routine medical supplies included in the rate. The statute does not provide for an exception for the removal of any or all supplies for certain type of patients from the PPS rate. We have used the best data available to calculate the non-routine medical supply component of the rates. We will continue to monitor the issue of non-routine medical supply costs with implementation of PPS.

Comment: Several commenters recommended that we re-examine the amount we added to adjust the LUPA per-visit amounts to account for non-routine medical supply costs. Many commenters suggested that the amount was inadequate, especially for wound care patients.

Response: As stated above, we have re-examined the issue of the appropriate level of non-routine medical supply costs in terms of wound care supplies and all non-routine medical supplies as they relate to all rates in the proposed rule, including the LUPA amounts. Based on comments, we have decided to increase the LUPA amount by paying the updated, prospective per-visit amount by discipline. We believe this per-visit amount accurately reflects an appropriate per-visit payment level, including medical supplies and other services furnished during LUPA visits. This provision is set forth in regulations at § 484.230. The revised LUPA approach is discussed in section IV.D. of this rule.

Comment: Commenters requested clarification of the application of 20 percent co-payment of non-routine medical supplies not related to the plan of care.

Response: Medical supplies are specifically listed in section 1861(m) of the Act as a covered home health service. All covered home health services are ordered by a physician for a patient under a plan of care. The 20 percent copayment does not apply to non-routine medical supplies covered as a home health service. There is currently no imposition of copayment on home health services except for DME. There is a 20 percent copayment on DME covered as a home health service. However, as stated above in section I.B. of this rule, BBRA of 1999 removed DME covered as a home health service from the consolidated billing requirements.

We note that Part B does not provide coverage of and payment for items termed ''non-routine medical supplies.'' DME may have a DME supply component, but that supply cost is related to the DME and included in the DME fee schedule payment. Further, the statute governing consolidated billing specifically refers to a patient under a plan of care. Providers cannot circumvent the consolidated billing requirements by attempting to exclude certain non-routine medical supplies from the plan of care by distinguishing between non-routine medical supplies related and unrelated to the plan of care. The comment may reflect concern with Part B services such as parenteral or enteral nutrition that are neither currently covered as home health services nor defined as a non-routine medical supply. Parenteral or enteral nutrition would therefore not be subject to the requirements governing home health consolidated billing because those Part B services are not home health services as defined in section 1861(m)of the Act. The applicable copayment or deductible requirements governing Medicare Part B outside of the Medicare home health benefit defined in section 1861(m) of the Act are not changed by this rule.

Comment: A few commenters stated that if a beneficiary has a continuing medical need for medical supplies due to a chronic illness unrelated to the condition the HHA is treating, the patient should be excluded from the PPS rate and consolidated billing.

Response: As we indicated in the proposed rule and the response to the previous comment, the law is very specific regarding the inclusion of medical supplies in the prospective rates. The law requires all services covered and paid on a reasonable cost basis as of the date of enactment of the BBA, including medical supplies, to be paid on the basis of a prospective payment amount under HHA PPS. The consolidated billing requirements at section 1842(b)(6)(F) of the Act, as amended by section 305 of BBRA, specifically require ''in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise).''

The statutory language governing consolidated billing clearly states that the patient is under the plan of care. If the patient requires medical supplies that are currently covered and paid for under the Medicare home health benefit during a certified episode under HHA PPS, the billing for those medical supplies falls under the auspices of the HHA due to the consolidated billing requirements. As stated in previous comments, there is no statutory latitude for an exception or carve-out of medical supplies from the PPS rate for patients under a plan of care under HHA PPS. We have included the costs of all such supplies in the rates.

Comment: A few commenters suggested that we establish clear guidelines so that providers of medical supplies receive adequate notice when items they may be furnishing to a beneficiary become subject to HHA PPS.

Response: The law refers to a patient under a home health plan of care. All routine and non-routine medical supplies that are currently covered as a Medicare home health service are subject to the home health PPS requirements. We believe the proposed rule and this final rule as well as current Medicare policies governing coverage of medical supplies under the home health benefit provide the notice of the requirements governing the HHA PPS. We will be directing our carrier to inform suppliers of this change and will be developing efforts to prevent erroneous billings. Further clarification of routine and non-routine medical supplies can be found in section 204.1 of the Medicare home health agency manual.

Comment: A few commenters suggested that we review the non-routine medical supply coverage policies of the various RHHIs and establish a consistent national coverage policy. Adjustments to the medical supply component of the rate should be made based on the analysis of the coverage variations in the original data used to establish the PPS rates.

Response: We have re-examined our approach to the national coverage policy governing non-routine medical supplies under the Medicare home health benefit. We do not have any indication of the existence of significant inconsistencies in coverage policies across RHHIs. As stated in previous comments, we will continue to monitor the coverage and utilization of non-routine medical supplies in subsequent years of PPS implementation.

Comment: Commenters suggested that medical supplies should be paid as used due to the wide variation in supply usage across patients and because some patients have historically paid out-of-pocket for supplies although HHAs were required to furnish them.

Response: As indicated above, the law specifically includes costs of medical supplies in determining the PPS rates. We are concerned that commenters even suggested that HHAs have historically permitted or even encouraged eligible Medicare beneficiaries to pay out-of-pocket for Medicare services that patients were not required to pay. We emphasize that agencies are obligated to furnish and Medicare will pay for needed medical supplies covered under the home health benefit.

C. Possible Inclusion of Medicare Part B Therapy Services in the Episode

Comment: We received a few comments regarding certain Part B therapy costs that were not included in the computation of the PPS rates. Several commenters suggested that we collect Medicare Part B Claims information for all therapy services provided to patients while receiving home health services under the home health benefit and adjust the episode definition, payment rate, and budget neutrality factor accordingly. Commenters believed that HHAs prior to PPS, as with non-routine medical supplies, had the option to unbundle therapy services outside of the home health benefit to Part B therapy providers. Because such services cannot be unbundled under PPS, commenters suggested that, based on our analysis of Part B therapy claims during a home health stay, an adjustment to the non-standardized amount should be made to account for this additional cost for therapy services.

Response: Before implementation of PPS, HHAs were not clearly prohibited from unbundling therapies to Part B. Consistent with our approach to non-routine medical supplies that could have been unbundled to Part B prior to PPS, we again analyzed Part B therapy claims data. Section IV.B.3. of this rule describes our claims analysis of the Part B therapy claims. Based on the analysis, we have adjusted the rates accordingly with the methodology described in section V. of this rule.

D. Continuous Episode Recertification

Comment: Several commenters support continuous episode certifications because the policy permits access to home health services for eligible beneficiaries. A few commenters requested clarification of continuous episode recertification with regard to long term utilizers of Medicare home health services. In addition, commenters requested further clarification of the definition of terms associated with continuous episode recertification. Some commenters requested specific clarification of the dates governing continuous episode recertification.

Response: We proposed continuous recertifications and payment, as appropriate, for beneficiaries who continue to be eligible for home health services. The payment system set forth in this final rule will permit continuous episode recertification for Medicare eligible beneficiaries. We believe this policy negates the need for a day or time (length of stay) outlier because beneficiaries will continue to be recertified for continuous episodes as long as they remain eligible for the Medicare home health benefit. In order to address the needs of longer stay patients, we are not limiting the number of 60-day episode recertifications permitted in a given fiscal year assuming a patient remains eligible for the Medicare home health benefit.

In response to comments, our explanation of the dates governing continuous episode recertification and clarification of terms associated with subsequent episode recertifications is given below. The first day of a subsequent second episode is day 61. The first day of all subsequent episodes, whether it is the second or third, etc. continuous episode, will be termed the ‘‘subsequent episode date.’’ The first day of a subsequent episode is not necessarily the first billable visit date. Unlike the initial episode, the first day of a subsequent episode may not occur on the first billable service date. Therefore, one must distinguish between the definition of the subsequent continuing episode date and the initial episode. Further technical examples of continuous care will be found in billing instructions that will be issued after publication of this rule.

E. Transition/Blend

Comment: Several commenters and most national industry associations supported full transition to a national rate. Conversely, only one industry association supported a four-year blend of agency-specific and national PPS rates. A few commenters suggested the continuation of IPS for the first certification or assessment period or next discharge date or a blend with IPS related data. A few commenters provided other creative alternative blend approaches that fell out of the scope of the statutory authority for the transition blend.

Response: Section 1895(b)(1) of the Act provides the option for a four-year transition to HHA PPS by blending agency-specific and national rates. We proposed full transition to the 60-day national episode rate. We believed blending cost based IPS with an episode rate was not a viable, effective option. After thorough re-examination of the comments and subsequent analysis, we continue to believe that full transition to national PPS rates without any blend of current IPS on October 1, 2000 is the most appropriate alternative. A blended rate system would be overly complex, distort the positive incentives in PPS, and reallocate limited resources from more efficient HHAs to less cost-conscious providers. A national PPS system has significant advantages over IPS. It recognizes case-mix and provides additional payments for higher cost outliers.

Comment: Several commenters objected to all HHAs being paid under home health PPS effective October 1, 2000. Many commented that this was unprecedented and recommended that the implementation date should be transitioned based on cost reporting year.

Response: The law governing the effective date for home health PPS implementation is very specific. In fact, section 5101(c)(1)(A) of OCESSA amended section 1895(a) of the Act to change the effective date for PPS from a transition by cost reporting periods to an immediate start-up date for all HHAs, effective October 1, 2000. The law, as amended, does not provide implementation by cost reporting period.

F. Split Percentage Payment

Comment: Current regulations require a physician signed plan of care before a HHA can bill Medicare for payment. Several commenters suggested the need to receive the initial percentage payment based on verbal orders. Many commenters were concerned about cash flow. Further, commenters believed that if we adopt a policy that permits initial payment based on verbal orders the need for a notice of admission would be eliminated.

Response: A number of commenters expressed concerns about cash flow to providers under the proposed system. Many reasons centered on the percentage of total payment provided upfront, as opposed to the end of the episode and the potential delays in receiving payments as a result of claims processing times, documentation requirements, and medical review. We appreciate these issues and are very interested in ensuring HHAs have adequate cash flow to maintain quality services to beneficiaries. As a result, we have taken a number of steps in this final rule that include increasing the amount of the initial percentage payment for initial episodes and a number of adjustments detailed below to significantly shorten the amount of time between the submission of the request for anticipated payment (defined below) and the receipt of payment. We believe these changes will significantly lessen the time for the receipt of payment as opposed to the approach set forth in the proposed rule. We are revising our approach to the split percentage payment as originally set forth in our proposed rule. We view the initial percentage payment as a ‘‘request for anticipated payment’’ rather than a Medicare ‘‘claim’’ for purposes of the Act. However, a request for anticipated payment is a ‘‘claim’’ for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the civil monetary penalties law (as defined in 42 U.S.C. 1320a–7a(i)(2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)). We also note that where we use the term ‘‘claim’’ in this final regulation, it refers to a ‘‘Medicare claim.’’ The first percentage payment will not require a physician signed plan of care before submission. The request for anticipated payment reflecting the initial percentage payment for the episode may be submitted based on verbal orders. All physician verbal orders must: (1) Be put in writing; (2) reflect the agreement between the home health agency and the physician with the appropriate detail regarding the patient's condition and the services to be rendered; (3) be compatible with the regulations governing the plan of care at

§ 409.43, § 424.22, and § 484.18; and (4) be signed by a physician prior to submission of the claim. In order to request anticipated payment for the initial percentage payment based on physician verbal orders, a copy of the plan of care with all physician verbal orders placed in writing and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4) responsible for furnishing or supervising the ordered service must be completed. A copy of the plan of care, which includes the verbal orders, must also be transmitted to the physician for his or her records. We believe this documentation need is consistent with current practice. Alternatively, the request for anticipated payment may be submitted if the HHA has a signed referral prescribing the physician's detailed orders for the services to be rendered and the patient's condition. Signed orders must, however, be obtained as soon as possible and before the submission of the claim for services is submitted for the final percentage payment for each episode. The final percentage payment including all of the utilization data for the episode is the Medicare claim. The claim for the residual final percentage payment requires a signed plan of care prior to billing for payment. Since the request for anticipated payment may be submitted based on verbal orders that are copied into the plan of care with the plan of care being immediately submitted to the physician and is not considered a Medicare claim, the request for anticipated payment will be canceled and recovered unless the claim for the episode is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the anticipated payment. The request of anticipated payment for the initial percentage payment is a request for payment of anticipated services. The claim for final payment of the residual percentage payment constitutes the claim for services furnished. We believe this revised approach to split percentage payment will alleviate cash flow concerns raised in the public comments. We revised current § 409.43(c) governing physician signature of the plan of care. Specifically, paragraph (c)(1) of this section specifies, "If the physician signed plan of care is not available, the request for anticipated payment of the initial percentage payment must be based on—

• A physician's verbal order that—

++ Is recorded in the plan of care;

++ Includes a description of the patient's condition and the services to be provided by the home health agency;

++ Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and

++ Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

• A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician."

In paragraph (c)(2) of this section, we specify that "HCFA has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraphs (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a "claim" for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2), and the Civil False Claims Act (as defined in 31 U.S.C. 3729(c), and the Criminal False Claims Act (18 U.S.C. 287), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment."

Paragraph (c)(3) of this section specifies that "The plan of care must be signed and dated—

• By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter and;

• Before the claim for each episode for services is submitted for the final percentage payment."

Paragraph (c)(4) of this section specifies that "Any changes in the plan must be signed and dated by a physician."

We agree with the commenter and believe that our revised approach eliminates the need for an additional notice of admission as originally proposed. We believe that the requests for anticipated payment of the initial percentage payment based on physician verbal orders responds directly to commenters concerns with current requirements governing physician signatures prior to claim submission. Commenters were concerned that the current signature requirements could disrupt necessary cash flow under PPS. We believe the request for anticipated payment for the initial percentage payment alleviates the cash flow concerns. Further, the request for anticipated payment of the initial percentage payment will provide appropriate cash flow to all providers because the requests are not subject to the current payment floor processing restrictions. The revised request for anticipated payment approach to the split percentage payment ensures adequate cash flow to providers who rely on Medicare resources to ensure continued quality care. Both the request for anticipated payment and the claim will be subject to medical review determinations. Subsequent payment withholdings may occur, as applicable. If a provider is targeted for medical review due to a history of excessive claim denials, it may not be able to submit requests for anticipated payment.

Comment: In the proposed rule, we proposed a 50/50 split percentage payment approach to the 60-day episode payment. The majority of commenters recommended a higher initial percentage payment in order to recognize the front loading of administrative costs associated with patient admissions. Many commenters requested increasing the initial percentage payment on at least the first episode due to the up-front costs associated with new patients.

Response: Based on comments that we have received, we believe the public has raised serious issues regarding cash flow under PPS. Therefore, we have re-evaluated our original split percentage proposal and have decided to revise our proposed approach to incorporate a 60/40 split for all initial episodes in order to recognize the up-front costs associated with new admissions. This new split percentage payment approach for all initial episodes is set forth in regulations at § 484.205(b)(1). All subsequent episodes will be paid at the 50/50 percentage payment split. The split percentage payment approach for subsequent episodes is set forth in regulations at § 484.205(b)(2). We believe our revised approach to the split percentage payment will provide appropriate financial relief to HHAs, adequate cash flow, and preserve the integrity of the Medicare trust funds. We believe our revised approach to the split percentage payment to include both the higher up-front percentage for first episodes and the submission of the request for anticipated payment of the initial percentage payment based on verbal orders, alleviates the cash flow issue for non-PIP providers as well as ongoing cash flow issues for PIP providers. PIP providers will receive their last September PIP payments during October. That continuing payment flow during the transition combined with the ability to submit all requests for anticipated payment of the initial percentage payment based on verbal orders at the onset of PPS will ensure adequate cash flow to PIP providers. The ability to submit all requests for anticipated payment of the initial percentage payment based on physician verbal orders responds directly to commenters concerns with current requirements governing physician signatures prior to submission of the claim. Commenters were concerned that the current signature requirements could disrupt necessary cash flow under PPS. We believe the request for anticipated payment for the initial percentage payment alleviates the cash flow concerns. Further, the request for anticipated payment of the initial percentage payment will provide appropriate cash flow to all providers because the requests are not subject to the current payment floor processing restrictions. We plan to continue to study the up-front rate of utilization under PPS.

G. Statutory Elimination of Periodic Interim Payments (PIP)

Comment: The majority of commenters recommended the reinstatement of PIP or a PIP-like accelerated payment under PPS to ensure adequate cash flow to PIP providers as well as all providers. One commenter specifically suggested accelerated payments for high volume HHAs.

Response: Section 4603(b) of the BBA amended section 1815(e)(2) of the Act to eliminate periodic interim payments. PIP payments are a method to periodically pay in advance before receiving a claim. Accordingly, we proposed to revise § 413.64(h)(1) to eliminate PIP for HHAs for services furnished on or after October 1, 2000. In this final rule, we are also removing paragraph (h)(2)(iv) of this section to comply with the BBA requirement that eliminates PIP for home health services upon implementation of PPS.

Based on comments received, we believe the public has raised critical issues regarding the need to provide adequate cash flow to all providers and specifically to PIP providers during the transition to PPS. However, traditional PIP is related to cost-based payment reconciliations and cannot be readily adopted to PPS rates.

As stated previously, we believe our revised approach to the split percentage billing to include both the higher up-front percentage for first episodes and the submission of the request for anticipated payment of the initial percentage payment based on verbal orders, that are copied into the plan of care with the plan of care being immediately submitted to the physician, eliminates the cash flow issue for non-PIP providers as well as ongoing cash flow issues for PIP providers. With regard to transition payments to PIP providers, they will be receiving their last September PIP payments during October. That continuing payment flow during transition combined with the ability to submit all requests for anticipated payment of the initial split percentage payment at the onset of PPS as of October 1, 2000, will also ensure adequate cash flow to PIP providers. We believe our revised methodology will reduce payment flow issues and meet the needs of all providers equitably.

In addition, accelerated payments, as historically available, may be available to HHAs that are disadvantaged by delayed payments due to unanticipated HCFA claims processing system failures or delays to ensure adequate cash flow. In regulations at § 413.64(g) for cost-reimbursed providers, and in §§ 412.116(f) and 413.350(d) for hospitals and skilled nursing facilities, respectively, that receive payment under a prospective payment system, we have provided for the availability of accelerated payments for non-PIP providers in certain situations. We do not believe that HHAs should be penalized for unanticipated claims processing system delays and are extending the availability of accelerated payments to all HHAs under PPS. Therefore, we are adding a new § 484.245 to provide HHAs the ability to request accelerated payments under home health PPS if the HHA is experiencing financial difficulties due to delays by the intermediary in making payment to the HHA.

H. Low Utilization Payment Adjustment (LUPA) (§ 484.230)

Comment: Commenters on the LUPA centered on such issues as the total elimination of the LUPA, retaining the four or fewer visit threshold at a minimum, the lack of recognition of additional costs associated with the first visit in the episode due to patient admission responsibilities, negative impact on rural and small providers, and the inadequate payment amount proposed for each standardized per-visit amount per-discipline. Many commenters suggested we increase the proposed LUPA amounts to reflect the current per-visit limits by discipline or cost per visit by discipline or by a percentage increase approach. A few commenters suggested the elimination of LUPA for the first episodes, but supported application of the LUPA for subsequent episodes.

Response: We proposed a low utilization payment adjustment in order to moderate provision of minimal or negligible care, that is, to discourage HHAs from providing a minimal number of visits in an episode. We proposed episodes with four or fewer visits be paid the wage adjusted national standardized per-visit amount by discipline for each of the four or fewer visits rendered during the 60-day episode. We solicited comments on the most appropriate threshold and specifically solicited comments on the use of the higher threshold of six or fewer visits. We will retain the original four or fewer visit threshold as no commenters supported moving the threshold to six or fewer visits. In this final rule, we respond to the recommendation to increase the proposed LUPA amount by now calculating the LUPA based on a higher national average per-visit amount by discipline updated by the market basket to FY 2001. This will provide a higher level of payment and fully compensate HHAs for such visits. We are revising our regulations at § 484.230 to reflect the higher per-visit amounts that will be used to calculate the LUPA payments. We are not adopting the comment to increase the payment only for the first visit to account for the front-loading of costs in an episode because we believe the approach set forth in this rule will adequately account for the costs for low utilization episodes. We will continue to monitor the impact of the four or fewer visit threshold and the revised LUPA per-visit amounts on all types of providers under PPS. The revised LUPA methodology and rate tables are found in section IV. of this rule.

Comment: Commenters suggested that we apply LUPA only to acute patients and not to chronic patients who require B–12 injections or catheter changes.

Response: The LUPA payment approach does not distinguish between an acute or chronic home care patient. The goal of the LUPA is to appropriately pay for low utilization episodes. As stated above we have revised § 484.230 to reflect the higher per-visit amounts that will be used to calculate the LUPA payments. We believe the revised approach to calculating the LUPA per-visit amounts by discipline will more adequately reflect average costs associated with low volume episodes.

Comment: A few commenters suggested the removal of wage index adjustment in the LUPA payment approach. Commenters also suggested that we case-mix adjust the LUPA.

Response: The LUPAs are not case-mix adjusted because they are calculated using national claims data for episodes with four or fewer visits. The claims data is only wage adjusted, not case-mix adjusted. We believe it is important to adjust the labor component of the LUPA based on the most recent pre-floor and pre-reclassified hospital wage index as historically reflected in the labor portion of home health services.

Comment: One commenter requested clarification of whether telephone contact or a telemedicine visit will count as a visit for purposes of the LUPA policy.

Response: The current definition of a Medicare home health visit has not changed with the implementation of home health PPS. The definition of a visit is set forth in § 409.48(c) of the regulations specifies that ''A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service.'' A telephone contact or telemedicine visit does not meet the definition of a visit and therefore would not count toward a LUPA visit.

Comment: A few commenters requested clarification of the type of practitioner that would provide a LUPA visit.

Response: The current personnel qualifications and coverage guidelines governing the provision of covered home health services are not changed by home health PPS. All visits provided under HHA PPS regardless of the provision under an episode rate or LUPA rate must meet current Medicare coverage guidelines.

Comment: A few commenters requested a specific HHRG level for LUPA cases.

Response: We do not believe the case-mix weight methodology as proposed would accommodate an HHRG specific weight for the LUPA. The LUPA is a wage adjusted per-visit payment. Constructing a LUPA specific HHRG would confuse the concept of case-mix adjustment and per-visit payment for LUPAs. However, we will continue to consider this proposal as we further refine PPS in the future.

I. Partial Episode Payment Adjustments (PEP Adjustment)

Comment: Several commenters did not support the use of billable visit dates to calculate the PEP adjustment due to possible gaps in days that may not be recognized in the payment. Many commenters recommended the use of the first billable visit date through the day before the intervening event or discharge date as the span of time used to calculate the proportional payment. Many commenters did not believe the PEP reflected the increased costs associated with admission during the start of the episode. Commenters proposed eliminating the proportional payment aspect of the provision thus yielding a full episode payment for the initial HHA and a full episode payment for the HHA receiving the patient due to the intervening event. Several commenters provided alternative payment approaches to the PEP policy as set forth in the proposed rule.

Response: In the October 28, 1999 proposed rule, we proposed a PEP Adjustment to address the key intervening events of the beneficiary elected transfer to another HHA and the discharge of a beneficiary who returns to the same HHA during the 60-day episode. We proposed to restart the 60-day episode clock due to the two intervening events and end the original episode payment with a proportional payment adjustment. The proportional payment adjustment would be calculated by using the span of billable visit dates prior to the intervening event. We are not adopting the commenters' suggestions to use the day before the intervening event or discharge date to calculate the proportional payment. We are retaining the use of billable service dates to determine the appropriate payments because of the HHAs involvement in decisions influencing the intervening events for a beneficiary elected transfer or the beneficiary is discharged and returns to the same HHA during the same 60-day episode period. Proportional payments based on billable visit dates will continue to be the payment methodology for the initial HHA as a result of the intervening event. We believe the new 60/40 percentage payment split for first episode payments as specified in regulations at § 484.205(b)(1) will alleviate concerns with costs associated with new patients.

Comment: A few commenters requested clarification of the calculation of the therapy hour threshold in the case of the transfer PEP Adjustment.

Response: The therapy threshold will apply separately to the proportional portion of the first episode and the new episode that results from the intervening event. The initial HHA will have the period of time of the first billable service date through the last billable visit date in the original plan of care prior to the intervening event to reach the therapy threshold. The new episode resulting from the intervening event will not incorporate therapy usage from the prior period but will determine the therapy needs for the patient resulting from the new certified plan of care. Each part of the episode, the PEP adjusted portion and the new 60-day episode resulting from the intervening event is subject to separate therapy thresholds. The therapy threshold is not combined or prorated across episodes. Each episode whether full or proportionally adjusted is subject to its own unique therapy threshold for purposes of case-mix adjusting the payment for that individual patient's resource needs. This PEP approach to the therapy threshold applies to both intervening events of the beneficiary elected transfer and the discharge and return to the same HHA during the same 60-day episode period.

Comment: Several commenters suggested the elimination or modification of the proposed policy that prevents the PEP adjustment when a beneficiary elects to transfer to an HHA that is under common ownership with the initial HHA. We proposed that transfers among HHAs under common ownership would be paid as an under arrangement situation. Commenters believed that the proposed common ownership policy should not apply when the transfer was made because the patient moved out of the first HHA's geographic service area defined by the agency's license. Further, commenters were concerned that if the proposed language regarding common ownership was not changed to conform to the rules currently governing related parties, it would be viewed as an attempt by HCFA to pierce the corporate veil and offset the liabilities of one corporation against payments due to another.

Response: In response to these concerns, we are providing further clarification of our definition of common ownership for purposes of the PEP adjustment for beneficiary elected transfers. If an HHA has a significant ownership interest as defined in § 424.22 (Requirement for home health services), then the PEP adjustment would not apply. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the ownership interest until the end of the episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moved out of their MSA or non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA not only serves as the billing agent, but must also exercise professional responsibility over the arranged-for services in order for the services provided under arrangements to be paid.

Comment: A few commenters requested that we clarify how we apply our PEP policy when a home health patient elects hospice before the end of the episode. The comments focused on a hospice that is under common ownership with the HHA.

Response: If a patient elects hospice before the end of the episode and the patient did not experience an intervening event of discharge and return to the same HHA, or transfer to another HHA during an open 60-day episode prior to the hospice election, the HHA receives a full episode payment for that patient. Upon hospice election, the beneficiary is no longer eligible for the home health benefit. The common ownership restriction for the PEP adjustment applies only to the relationship between two HHAs providing covered home health services to a home health eligible beneficiary.

Comment: A few commenters requested clarification of whether a PEP adjustment will apply to the initial HHA when a physician or patient-initiated termination of home health services occurs and the treatment goals have not been reached. In addition, commenters further requested clarification of the beneficiary elected transfer PEP policy when the beneficiary transfers because the HHA provided minimal or negligible services.

Response: To account for the situation when a patient initiates the termination of services for any reason and requests a transfer to another HHA, we developed the PEP adjustment to assure that the patient's freedom of choice was honored and that the Medicare Trust funds were protected by a policy that ensures adequate payment levels that reflect the time each HHA served the patient under a transfer situation. Unless the beneficiary refused further care or was a safety risk to the HHA staff, we do not envision a situation in which a physician would terminate care prior to the completion of treatment goals. However, we would focus survey or medical review resources to investigate complaints of minimal or negligible service delivery as a motivating factor for a beneficiary's election to transfer from the original HHA.

Comment: A few commenters suggested that we allow the physician to reinstate the initial plan of care rather than requiring a new plan of care in the situation of discharge and return to the same HHA during the same 60-day episode.

Response: We are not adopting this comment. We believe that a new certified plan of care is a critical feature of any episode payment, regardless of whether prior treatment goals were met and the patient was formally discharged. We do not believe that it is unduly burdensome because the HHA will be receiving access to an entire 60-day episode payment. Further, a patient that returns to the HHA for admission after discharge would require a new OASIS assessment and new plan of care under current practice guidelines.

Comment: Some commenters asked if the PEP adjustment is applied when a patient dies.

Response: A full episode payment will be paid in the event of a patient's death during a 60-day episode. No PEP adjustment will be calculated due to a patient's death during an episode.

Comment: A few commenters argued that the PEP adjustment policy approach does not adequately address ''snow birds'', persons who seasonally migrate from one place to another.

Response: We believe the PEP adjustment will adequately address this situation. As stated previously, if for any reason, a beneficiary elects to transfer to another HHA, the original HHA's episode payment would be proportionately adjusted with a PEP adjustment to reflect the time the HHA served the patient prior to the intervening event of the transfer. This would include the ''snow bird'' situation. We do not believe there is a need for an exception from the transfer policy regarding ''snow birds''. Our PEP adjustment policy governing transfers provides for a clean slate for a 60-day episode payment, OASIS assessment, and certification for the receiving HHA. We believe this is an equitable approach to intervening events during the 60-day episode.

Comment: Commenters argued PEP adjustment governing discharge and return should not apply when there is a readmission for the same diagnosis. Commenters stated that the discharge and return to the same HHA during the 60-day episode PEP adjustment requires the goals in the original plan of care to be met prior to discharge. Commenters requested further clarification of meeting treatment goals in the original plan of care.

Response: We will not provide for payment for two full episodes at any time during a given certified 60-day episode. If an HHA discharges a patient, it is assumed that the patient has met the course of treatment set forth in conjunction with physician orders in the patient's original plan of care. If the patient returns with the same diagnosis, it may not indicate the same plan of care. Even if the HHRG level did not change upon return, the patient's initial discharge indicated completion of the original course of treatment. The original episode payment would be proportionately adjusted to reflect the time prior to discharge with a PEP adjustment.

J. Significant Change in Condition Payment Adjustment (SCIC Adjustment) (§ 484.237)

In the October 28, 1999 proposed rule, we proposed a significant change in condition adjustment to recognize the event of a significant change in patient condition that was not envisioned in the original plan of care. The SCIC adjustment is calculated as a proportional payment reflecting the time both before and after the patient experienced the significant change in condition. Billable visit dates are used to calculate the proportional payments.

Comment: Some commenters did not support the use of billable visit dates due to the potential gaps in payment days used to calculate the SCIC adjustment. Commenters suggested using the dates that the patient received comprehensive case management or all the days in the 60-day episode. Many commenters suggested the restart of the 60-day episode clock due to the patient's significant change in condition, resulting in two full episode payments or a prorated payment plus a full new episode payment. Other commenters suggested that the admission to an inpatient facility should indicate close of a previous episode for outcome data collection, similar to the PEP proportional payment approach. Other SCIC comments centered on prorating payments based on visits or increasing the SCIC proportional payments by an equitable percentage increase to each proportional payment for the original diagnosis.

Response: The use of billable visit dates as the boundaries for the payment adjustment encourages appropriate service use and supports the delivery of all needed care. We further believe that the current SCIC adjustment policy provides financial relief to HHAs who would otherwise be locked into a case-mix adjusted payment based on a point in time of the patient's condition at the beginning of the episode. We will retain the current SCIC adjustment policy and are not adopting the commenters' suggestions. The SCIC adjustment ensures HHAs will have adequate resources to meet the changing patient needs of its mix of patients. The SCIC adjustment provides HHAs with the ability to meet the changing resource needs of their patients.

Comment: Many commenters requested clarification, and others requested removal, of the policy set forth in the preamble of the proposed rule governing intervening hospital stays during a 60-day episode. In the proposed rule, we stated that if a patient experiences an intervening hospital stay during an existing 60-day episode under an open plan of care, then the patient would not have met all of the treatment goals in the plan of care. Therefore, the intervening hospital admission during an existing 60-day episode could result in a SCIC adjustment, but could not be considered a discharge and return to the same HHA PEP adjustment. Currently, HHAs are provided the option to discharge patients upon transfer to an inpatient facility.

Response: We believe that HHAs should be given the option to discharge the patient within the scope of their own operating policies; however, when an HHA discharges a patient as a result of a hospital admission during the 60-day episode that discharge will not be recognized by Medicare for payment purposes. Either an intervening hospital stay will result in an applicable SCIC adjustment or if the Resumption of Care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60-day episode payment will be provided spanning the home health episode start of care date prior to the hospital admission, through and including the days of the hospital admission, and ending with the 59th day from the original start of care date of the episode.

Comment: Commenters requested clarification that the SCIC adjustment will only apply in cases of deterioration, that is, increased payment due to a new HHRG and not improvement resulting in a possible decrease in payment for the second part of the SCIC adjustment.

Response: We designed the SCIC adjustment to permit the HHA to adjust the assessment and the concomitant HHRG assignment when the patient's condition changes in a significant way that was unanticipated in the context of the initial assessment. The SCIC adjustment will occur in both situations of significant patient deterioration and improvement. Excessive use of the SCIC adjustment for patient deterioration will be monitored under PPS to ensure the legitimacy of claims for increased payment.

Comment: A few commenters asked if there is a limit to the number of SCIC adjustments in one 60-day episode.

Response: Although there is the clinical possibility of more than one SCIC adjustment during a given 60-day episode, we believe it will be a rare occurrence. While we will permit more than one SCIC per episode, providers who demonstrate a pattern of multiple SCIC adjustments will likely be subject to review to assure the validity of such situations.

Comment: Several commenters suggested the use of a modified OASIS assessment for purposes of SCIC Adjustments. Commenters requested that we require only those OASIS and other items necessary for case-mix for the determination of a SCIC adjustment.

Response: Totally apart from PPS, the current protocol governing OASIS assessment schedules, requires the complete OASIS assessment at points in time when the patient experiences a significant change in condition. Further, we believe it is necessary to have all OASIS items relevant for outcome measures to monitor the use of SCIC adjustments under PPS. We are not adopting this comment on the approach to SCIC adjustments. The SCIC adjustment provides an additional payment adjustment without which PPS would have locked the HHA and patient in a 60-day episode payment level according to the patient's status at the beginning of the 60-day episode. We do not believe the completion of the full OASIS assessment generates a cost that outweighs the benefit of the SCIC adjustment from a payment and quality of care perspective.

Comment: Commenters had additional questions regarding our policies governing the SCIC adjustment. Specifically, commenters asked if physician verbal orders would suffice to precipitate a SCIC adjustment or would the form 485 have to be completed.

Response: The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during the 60-day episode that was not accounted for in the original plan of care. In order to receive a new case-mix assignment for purposes of the SCIC adjustment payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain necessary change orders reflecting the significant change in treatment approach in the patient's plan of care. While the physician's verbal order and the corresponding OASIS reassessment may precipitate the new case-mix level and corresponding payment grouping the HHRG for the balance of the 60-day episode, the SCIC adjusted episode, like any other episode, requires a signed plan of care prior to submission of the claim for the final percentage payment.

Comment: Commenters requested clarification of whether the LUPA will apply in situations of the SCIC adjustment.

Response: A SCIC adjusted episode payment could be further adjusted to reflect the LUPA, if applicable. However, because a LUPA payment is not case-mix adjusted, the SCIC would have no payment consequence on an episode paid at the LUPA level. This would be a limited, but not inconceivable, occurrence that would likely be targeted by medical review.

K. Case-Mix

Caregiver Variables on OASIS Not Used in Case-Mix System

Comment: In the proposed rule we stated that caregiver variables would be omitted from the case-mix model. Some commenters were concerned that failure to consider caregiver availability may result in inadequate payment. One commenter stated that returning to independence or assuming care on a long-term basis often depends on the patient's support system or lack thereof. Commenters stressed that caregiver availability is a particularly strong factor in rural areas where patients have fewer community supports to make up for the lack of caregiver assistance in the home.

Response: In the proposed rule, we discussed our basis for excluding such variables. We recognize that adjusting payment in response to the presence or absence of a caregiver may be seen as inequitable by patients and their families. To the extent the availability of caregiver services, particularly privately paid services, reflects socioeconomic status differences, reducing payment for patients who have caregiver assistance may be particularly sensitive in view of Medicare's role as an insurance program rather than a social welfare program. Furthermore, adjusting payment for caregiver factors risks introducing new and negative incentives into family and patient behavior. It is questionable whether Medicare should adopt a payment policy that could weaken informal familial supports currently benefiting patients at times when they are most vulnerable.

Notwithstanding these considerations, we examined the usefulness of caregiver factors but found them to be only minimally helpful in explaining or predicting resource use. A variable on the availability of a caregiver had no impact on average resource cost (Abt Associates, Second Interim Report, September 24, 1999), and only a modest impact after controlling for other patient characteristics (Abt Associates, First Interim Report, July 1998 [Revised December 1998]). This could result if patients who are able to remain in the home without a caregiver are inherently less impaired and more able to provide self-care than other home care patients. (One commenter seemed to confirm this hypothesis in stating that caregiver availability can determine whether a patient can safely live at home.) A strong relationship between caregiver assistance and patient health/functional status could make it difficult analytically to identify a cost impact resulting from the caregiver's lack of availability. As a technical matter, this problem could hinder accurate incorporation of caregiver availability into the case-mix system, were it deemed appropriate.

Results from the Phase II per-episode prospective payment demonstration lend credence to the limited value of caregivers in explaining resource use under a PPS system. Evaluation of the demonstration indicated that reductions in service utilization among PPS patients were the same, regardless of whether the patient had other caregiving (Mathematica Policy Research, Inc., ''Per Episode Prospective Payment for Medicare Home Health Care Sharply Reduces Service Use,'' Draft Report, December 1998). The findings suggest that, despite intentions to rely more heavily on other caregivers as a way of reducing home care costs, PPS agencies did not target their service reductions more heavily on patients with caregivers. The reason for this outcome is unclear. (There was also little or no indication that PPS agencies tried to avoid patients without caregivers.)

Other caregiver variables examined in the case-mix study, measuring frequency of assistance and caregiver health/psychosocial status, also exhibited a relatively modest impact on resource cost. When added to the existing model they added less than one point to the model's explanatory power (R-squared) (Abt Associates, Second Interim Report, September 24, 1999). These findings weaken the assertion that failure to adjust for caregiver factors could render payments inadequate. It should also be noted that, based on preliminary data, these caregiver variables did not have particularly strong item reliability (Abt Associates, Second Interim Report, September 24, 1999, Appendix G). Low reliability means an assessment item is prone to mis-measurement. In measuring case-mix for payment purposes, we wish to avoid, to the extent possible, items with weaker reliability. (We will continue to examine the reliability data as they are finalized.)

In summary, we believe that in light of data that support our policy concerns surrounding caregiver variables, and their insignificant contribution to predicting resource use, these OASIS items are not appropriate for use in the case-mix adjuster.

Comment: Several commenters urged us to continue to study the issue of caregiver impacts, including further study of language used in the caregiver items for the OASIS.

Response: We will continue to examine OASIS caregiver variables and their impact as we analyze national OASIS and claims data to pursue refinements to the case-mix system. However, in the absence of policy consensus that caregiver variables are appropriate to include, it would not be cost-effective to commission further studies of alternative wording of caregiver-related assessment items.

Variables Identifying Preadmission Location in the Services Utilization Dimension

In the proposed rule we set forth a services utilization dimension within the case-mix model. We proposed including variables indicating whether certain inpatient stays occurred in the 14-day period immediately preceding the home health episode. Not only are pre-admission inpatient stays a traditional indication of need in clinical practice, but also such variables were useful correlates of resource cost in our analyses of the case-mix data (Abt Associates, First Interim Report, July 1998 [Revised December 1998], Abt Associates, Second Interim Report, September 24, 1999).

Comment: Several commenters requested clarification about the derivation of the scores and severity grouping in the services utilization dimension.

Response: Our data indicate that an acute care hospital discharge (without follow up post-acute inpatient stay) within the 14 days immediately preceding admission to home care is associated with the lowest costs during the 60-day episode. Other research has shown similar findings. For example, in the home health Phase II per-episode prospective payment demonstration research, multivariate analysis of home care utilization in the year following admission also suggested that pre-home-care hospital stays were associated with reduced home care utilization. In the case-mix data, episodes involving patients with no pre-admission inpatient stay had the second-lowest cost; episodes involving patients who had both a hospital and post-acute-care institutional stay (that is, skilled nursing facility (SNF) or rehabilitation facility) had the third-lowest cost; and episodes involving patients who had only a SNF or rehabilitation facility stay had the highest cost. The highest-cost category (SNF or rehabilitation stay alone, given a 14-day window) may actually be comprised predominantly of relatively long stays. These stays appear to be indicators for patients who, upon their return home, have high care needs during the 60 days following home health admission.

In the case-mix data, if a patient who had a hospital stay in the 14 days preceding admission is evaluated to need significant home therapy, then the resource costs increase sharply. Likewise, therapy utilization markedly increased resource cost for the episodes preceded by the other three pre-admission locations. Because the therapy utilization was to be considered simultaneously with the preadmission location in the services utilization dimension, we examined the resource cost according to eight categories. These eight categories are the four pre-admission locations (hospital stay alone, no inpatient hospital or SNF/rehab stay, a hospital-stay-plus-SNF/rehab-stay, or a SNF/rehab stay alone) with and without therapy utilization of at least eight hours.

The resulting array of average resource cost indicated that among episodes not meeting the therapy threshold, those following a hospital stay, no inpatient hospital or SNF/rehab stay, or a hospital-stay-plus-SNF/rehab-stay all had similar resource costs. We assigned increasing scores—zero to 2—for these groups, in accordance with the trend in the data overall, but ultimately grouped them into a single severity level reflecting their similar resource costs. Episodes not meeting the therapy threshold but with a SNF/rehab stay alone were effectively assigned a score of three (from the combination of scoring for the hospital stay and SNF/rehab response categories) and grouped separately into the second severity level, because their resource cost was significantly higher than patients with a score of zero to 2.

The remaining two severity groups were for episodes that met the therapy threshold. Therapy-threshold patients coming from the first three locations were grouped together into a third severity level because of the similarity in their resource costs. Scoring for these patients again reflected the overall trend by preadmission location (scores of zero, one, and two for hospital stay, no inpatient hospital or SNF/rehab stay, or a hospital-stay-plus-SNF/rehab-stay, respectively) but included an additional four points to reflect the cost impact of the therapy. High-therapy patients from the fourth pre-admission location (SNF/

rehab stay alone) had the highest costs of any group, so we placed them in the fourth and final severity category. Following the existing scoring logic, these episodes had a total score of seven based on three points for the preadmission location and four points for the therapy need.

Comment: Some commenters stated that their own experience did not confirm the relationship between pre-admission institutional stays and resource cost as indicated in our case-mix research data. Specifically, commenters indicated that patients coming from the hospital are often more acutely ill and resource-intensive than other patients, particularly patients who had no preadmission institutional care. For example, these patients typically need more frequent visits and teaching. As a result, according to these comments, the case-mix system fosters a disincentive to admit post-acute-hospital patients.

Response: The conclusion reached by the commenters is incorrect because the severity grouping (though not the scoring) is neutral with regard to pre-admission hospital stays. Patients with such stays, as well as patients without any institutional stays, and patients with hospital-plus-SNF/rehab care, are all grouped together in the same severity category. The patients who were admitted with only a SNF/rehab stay in the previous 14 days are grouped into a separate severity category. Within each of these two severity categories, the patients meeting the therapy threshold are split off into an analogous severity category reserved for therapy patients. It is the severity category that determines the case-mix weight. (In the services utilization dimension, the scoring system is simply a device to organize the assessment data on preadmission location and therapy threshold.)

Comment: Several commenters suggested that the 14-day definition for the preadmission location on OASIS actually encompasses a heterogeneous group of patients, and that comparison of patients admitted to home care within 1 or 2 days of discharge with patients admitted within 5 to 14 days of discharge would reveal a cost difference.

Response: While this distinction or others related to the time since discharge might prove useful, the OASIS assessment does not provide the level of detail necessary to recognize any difference. In analyzing the data available to us, we examined the cost separately for the subset of patients who experienced a SNF/rehab stay as well as an acute care stay (and thus were unlikely to be among the patients admitted to home care within one to two days of discharge). This subset of patients was generally about as costly as the hospital-stay-only patients. This suggests that in the absence of the SNF/rehab stay, the agency would have otherwise incurred higher resource costs by admitting the patient to home care directly from the acute-care-hospital. The timing of the home health admission is to some extent correlated with SNF use, which in turn may be correlated with case severity. Under these conditions, it may be difficult to quantify a suspected relationship between the timing of the admission and resource use. (This is similar to the comment noted earlier concerning caregiver variables; that is, a variable such as caregiver availability or SNF use may tend to offset resource cost for particularly costly patients, making it difficult to observe the relationship between these patients' severity and their presumed costliness.) We will continue to examine this issue in the future using claims and linked OASIS data.

Comment: Another comment stated that paying a higher rate for patients experiencing a pre-episode SNF or rehab stay puts rural agencies at a disadvantage, because many patients elect to return directly home from the hospital due to a shortage of post-acute institutional care facilities.

Response: As stated earlier, three pre-admission location categories are all grouped in the same severity level. The fourth category was grouped separately—patients experiencing only a SNF/rehab stay within the previous 14 days. As we noted in the proposed rule, these patients likely experienced a relatively long SNF stay, which appears to be an indicator for exceptionally high case severity. Whether such cases from rural areas systematically fail to be placed appropriately in post-acute-care institutions deserves further study. Our impact analysis suggests, however, that rural agencies will experience payment increases under PPS (see Table 11). Examination of payment-to-cost ratios in the Abt case-mix data also suggests that rural agencies will experience payments under the PPS system that exceed their historical cost levels (Second Interim Report, September 24, 1999).

Comment: One commenter stated that recent hospitalization affects the plan of care, particularly within the first 30 days. We also received a comment noting the costliness of care for ''chronic, long-term'' patients coming from the community as their pre-admission location, but with high clinical and functional severity.

Response: We emphasize that the resource cost used to develop the case-mix system was measured over the patient's first 60 days under the care of the HHA. Thus, it is entirely possible that patients with contrasting pre-admission locations could have similar total resource costs albeit with different care trajectories. For example, for relatively healthy patients who are bound for recovery from an acute illness, and who may therefore be discharged from home care fairly soon after a short, intensive period of teaching and support, the total 60-day resource cost may be comparable to the cost for certain chronically ill patients who have less-intensive but more sustained needs over the course of the 60-day episode.

Comment: A commenter urged us to revise the services utilization scoring of OASIS item M0170 because a patient coming from the community is similar in resource need to one coming from a rehabilitation hospital or SNF, but they have different scores on the services utilization category.

Response: We have not revised the scoring of M0170 because the combination of scoring for M0170, lines 1, 2, and 3, allows for differentiation between SNF or rehabilitation patients with and without hospital discharge. This distinction is important in case-mix system grouping.

Comment: Commenters also indicated concern about the accuracy of reporting on the OASIS for the preadmission location.

Response: We agree that assessing clinicians may have difficulty in some instances obtaining accurate data on the type of institution and the dates of discharge. The fact that the severity levels in the services utilization dimension are neutral with respect to most pre-admission location scenarios partially mitigates this concern. Assessing clinicians would be well-advised to confirm information with multiple sources (for example, the patient, family, referring physician, local hospital) to ensure its accuracy. The clinician may also ask to see the patient's discharge instructions. Virtually all institutional stays that require ascertainment for case-mix purposes are covered by Medicare. The National Claims History and other data bases eventually record these events, potentially affording Medicare's fiscal intermediaries opportunities for reviewing case-mix accuracy on a post-pay basis. We will instruct the fiscal intermediaries to take into consideration the challenges faced by agencies in accurately reporting the preadmission location, and formulate review policies accordingly.

Comment: A commenter expressed concern that preadmission location variables are a matter of timing for a service rather than a measure of acuity. The commenter questioned why a SNF discharge 16 days before would differ from one 14 days before home health admission.

Response: The preadmission location item M0170 was originally included in OASIS as one of many variables useful for risk adjusting outcome measures. A recent institutional stay (discharge within two weeks) continues to be a frequent event preceding home care. The two-week definition is unambiguous, and has proven statistical impact in both a case-mix and outcomes research context. Using a longer recall period would present measurement problems and would be less helpful in explaining resource use.

Comment: A commenter stated that the OASIS item on prior location (M0170) creates an artificial distinction between patients who received care in a rehabilitation wing of an acute care hospital and patients who received care in a rehabilitation facility.

Response: OASIS instructions define a rehabilitation facility as a freestanding rehabilitation hospital or a rehabilitation distinct part unit of a general acute care hospital. Therefore, a rehabilitation wing (that is, distinct part unit) is included in the OASIS rehabilitation facility definition.

Comment: A commenter stated that the language regarding nursing facilities was inconsistent between Table 7 in the proposed rule and OASIS. A related comment suggested that we clarify the response categories in OASIS item number MO170 to distinguish between stays in skilled nursing facilities and extended care facilities.

Response: We are revising the OASIS MO170 response categories to allow separate reporting of skilled nursing facility discharges within the previous 14 days. This change will resolve the inconsistency.

Comment: A commenter requested clarification of Case 1 in the proposed rule (page 58179) and asked whether the case information or Table 7 is correct.

Response: We apologize for this error in the case description. The Service Dimension should have read ''Service Domain=4 (therapy more than 8 hours).''

Comment: A commenter stated that there should be much less emphasis on where the patient is located and more on the patient's clinical needs.

Response: We included preadmission location information in the services utilization dimension because it has traditionally been associated with variation in home care services utilization, and in our case-mix research it helped to explain variation in home care resource use. We do not believe the case-mix system places excessive emphasis on this type of predictor variable. Clinical needs are addressed in the clinical dimension.

Variables Measuring Therapy Utilization in the Services Utilization Dimension

To ensure that patients who require therapy would maintain their access to appropriate services under the HHA prospective payment system, in the proposed rule we grouped patients according to their therapy utilization status. Specifically, we defined a therapy threshold of at least eight hours of combined physical, speech, or occupational therapy over the 60-day episode, to identify high therapy cases. We proposed a threshold of eight hours of therapy based on clinical judgment about the level of therapy that reflects a clear need for rehabilitation services and that would reasonably be expected to result in meaningful treatment over the course of 60 days. Subsequently, further development and refinement of the Abt case-mix model assumed this threshold as part of the grouper logic.

The 15-minute-increment billing requirement in principle allows the RHHI payment system to verify the case-mix therapy threshold. However, there is uncertainty about the completeness and accuracy of the 15-minute reporting. This led us to propose that, pending resolution of this issue, the therapy threshold be expressed in a defined number of visits. Returning to the resource use data of the Abt study, we determined that on average a therapy visit lasted approximately 48 minutes. This implies that on average eight hours of therapy would be exhausted in 10 visits.

Comment: Several commenters urged us to change the conversion to eight visits to be consistent with current cost reporting and salary equivalency practice equating one visit to one hour. Commenters suggested that, without such a change, the proposal effectively reduces therapy payments. Some commenters argued that a conversion to eight visits (or fewer—other commenters proposed six visits and four visits) would compensate for excluding time spent on a case outside of the home from the calculation of resource cost in the Abt study. In addition, commenters pointed out that some patients will achieve eight or more hours in fewer than 10 visits, so HCFA should recognize that the therapy threshold has been met as soon as the eight hours are achieved.

Response: We see no reason to associate the cost reporting and salary equivalency practices with the independent, congressionally mandated 15-minute-increment reporting requirement. The origin of this requirement was Congress's intent that adequate data be available to both develop and refine the HHA prospective payment system. We see these data potentially as key resources for improving the case-mix system in the future. Upon linking the claims with the OASIS assessments, a data resource comparable to the Abt case-mix study data will be available for research purposes. This resource promises to improve upon the Abt data by virtue of the large sample sizes it would provide. Many suggestions from commenters for improvements that need study can be pursued once these data are assembled. We believe there are advantages to the continued gathering of 15-minute billing information. We urge home health agencies to continue their diligent collection of these data so that eventually the therapy threshold can be used as originally defined—in terms of time spent in the home, not visits.

The PPS pricer developed for the first year of PPS will determine the case-mix adjustment based on the 10-visit threshold without consideration of the 15-minute-increment billing data on the claim. Upon analysis of national claims data under PPS, we will determine whether the pricer should be changed to take into account information from the 15-minute-increment reporting. We are concerned that counting visits rather than hours to satisfy the therapy threshold in the case-mix groupings could become a source of potential abuse. Therefore, if we identify providers whose therapy visits are systematically and significantly shorter than the 48-minute standard, yet meet the 10-visit threshold, we will examine such cases and reduce the case-mix assignment if evidence documents that therapy hours were well below the 8-hour threshold.

The commenters' suggestion that we compensate for excluded time spent outside the home by adopting a lower therapy threshold does not resolve a significant issue that requires further study. The commenters' proposal can result in diminished payment accuracy, because the relative weights are based on groups defined from the 8-hour threshold. If, over time, the composition of the therapy groups shifts to lower-cost patients, the relative weights would need to be adjusted accordingly.

If we adopted a lower therapy threshold or a graduated threshold, as some commenters suggested, we believe the result would be an increase in the incentive to maximize payment by manipulating the delivery of therapy. Comments proposing that Medicare prorate the therapy factor in transfer or in cases where the therapy utilization is spread over more than one episode, present problems for this reason as well. The comment suggesting that the therapy factor be prorated when utilization is spread over more than one episode appears to reflect a misunderstanding of our intent to have the therapy threshold, as applied within the 60-day episode, target patients with significant therapy needs. The rationale for recognizing a therapy utilization factor is to ensure that agencies will be adequately compensated for delivering this high-cost service, thus preserving access for patients with therapy needs. It is the same rationale that underlies case-mix adjustment itself. Payment weights for groups containing patients whose therapy utilization is spread over multiple episodes reflect the reduced resource costs of these patients per each 60-day episode. As discussed previously, in a PEP situation (for example, a transfer), the therapy threshold is separately measured for the proportional episode and the new episode resulting from the beneficiary elected transfer. In the SCIC situation, the therapy threshold applies to the total therapy visits provided to the beneficiary during the episode both before and after the significant change in condition occurred.

Further suggestions that skilled nursing time as well as aide time be measured and treated the same as therapy hours would also seem to reinforce these undesirable incentives, as skilled nursing visits make up the single largest discipline category in home health care, and aide visits the second largest, with both far outweighing therapy visits.

Comment: Several commenters questioned the decision to use a therapy threshold in the case-mix adjustment system.

Response: We recognize that, as we indicated in the proposed rule, using a utilization variable such as the therapy measure is susceptible to manipulation. However, currently our best available data requires us to rely in part on the therapy measure. Without it, we cannot achieve the preferred level of payment accuracy, notwithstanding its potential susceptibility to manipulation. We note that the case-mix system for home health is similar to the other major Medicare case-mix systems, in that these others also use measures of treatment planned or received. We will continue to review the use of a utilization variable in this system over the long term.

Comment: We received several suggestions from commenters that amounted to changing the group assignment for certain types of patients so that the payment weights for these patients would be comparable to or even higher than the existing therapy-group weights. For example, one suggestion was to award points to the services utilization dimension when the patient is assessed at the highest level of the clinical and functional dimensions. Another suggestion was to add points to the services utilization dimension when the patient is a user of multiple therapies, perhaps by defining a fifth severity level within the services utilization dimension.

Response: We appreciate these comments as they will aid us as we further refine the case-mix model. At this time, however, it is not clear that such changes would provide a satisfactory remedy for the problems the commenters have raised. In deciding on the basic structural characteristics of the case-mix system, we had to balance clinical acceptability, complexity, and technical issues, such as the feasibility of estimating payment weights from varying group sample sizes. Thus, suggestions that imply a larger number of groups must be evaluated in terms of their potential to impact the accuracy of the payment weights, the system's clinical logic add to, not lessen, the complexity of administering the system. Any grouping changes potentially affect the entire array of payment weights because they are relative values.

Comment: One commenter stated that it will be very difficult for agencies to comply with the requirement to project the number of therapy hours at the start of care, because physicians' orders in the plan of care do not typically indicate the number of anticipated therapy hours or visits.

Response: The Home Health Certification and Plan of Care (HCFA 485) requires the physician orders to specify the amount, frequency, and duration for disciplines and treatments. We expect agencies to make the projection from these orders.

Comment: A commenter sought confirmation that the reconciliation of projected therapy use with actual therapy services furnished during the 60-day episode has the potential to either decrease or increase final payment.

Response: The commenter is correct. The final payment may increase or decrease in response to a difference between the therapy projected at the start of care and the therapy received by the patient by the end of the 60-day episode.

Comment: A commenter stated that the Phase II per-episode prospective payment demonstration research indicated barriers to occupational therapy (OT) services under PPS. The commenter recommended that we consider a more interdisciplinary approach to OASIS so occupational therapy would not be underutilized.

Response: The therapy threshold in the case-mix adjuster is based on all three therapy disciplines combined. The design of the demonstration did not include a case-mix adjuster with a therapy threshold of any sort. It does not necessarily follow that the national PPS would introduce a barrier to OT services.

Comment: A commenter recommended that therapists should assess the patient's functional status to minimize errors in measurement. In addition, the commenter believes monitoring will be needed to prevent payment incentives from distorting functional assessment measurements.

Response: We expect that agencies will measure functional status as accurately as possible, consistent with incentives for efficiency in the prospective payment system. We have no authority to mandate functional status assessment by a particular discipline. We agree that medical review activities should include review of functional assessment results.

Comment: A commenter stated that, as a result of the therapy threshold, the case-mix system will divert utilization of the home health benefit away from the frail elderly and in favor of the short-term patient.

Response: It is not our intention to change access under the home health benefit through a case-mix adjusted prospective payment system. Moreover, the payment for continuous 60-day episodes of care under PPS will be more conducive to the care of longer stay patients than the current interim payment system. We expect that evaluations of the system's impact will study the question raised by this commenter.

Comment: A commenter recommended standardizing therapy visits in hours or 15-minute increments to meet the current statutory requirements of section 4603 of the BBA that specify that home health visits are reported in 15-minute increments.

Response: We have not accepted this recommendation. We believe this would